

COMPARISON OF THE EFFICACY OF POPULAR WEIGHT LOSS PROGRAMS IN
SEDENTARY OVERWEIGHT WOMEN

A Dissertation

by

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ABSTRACT

This study compared the efficacy of the Curves[®] Complete 90-day Challenge (CC), Weight Watchers[®] Points Plus (WW), Jenny Craig[®] At Home (JC), and Nutrisystem[®] Advance Select[™] (NS) on weight loss, body composition and/or markers of health and fitness in sedentary overweight women. One hundred thirty-three women (47 ± 11 yr, 86 ± 14 kg, $46 \pm 5\%$, 35.4 ± 6 kg/m²) were randomized into CC (n=29), WW (n=29), JC (n=27), NS (n=28), or control (n=20) for 12-wks. Self-recorded food logs (4-d), International Physical Activity Questionnaires, weight, resting energy expenditure (REE), dual energy x-ray absorptiometry, anthropometrics, and fasting blood samples were obtained at 0, 4, 8, & 12 wks. Peak aerobic capacity and muscular strength were measured at 0 and 12 wks. Data were analyzed by ANOVA or MANOVA with repeated measures.

Average energy intake was $1,403 \pm 427$ kcal/day with no differences among groups. CC was the only group with an increase in protein (0.15 ± 0.30 , $p=0.039$) combined with a reduction in carbohydrate (-0.63 ± 0.95 g/kg/day, $p=0.005$) intake. CC was the only group with a significant increase in total physical activity ($3,801 \pm 8,668$ MET-min/wk, $p=0.012$) through week 8. All diet groups experienced a decrease in weight (-4.0 ± 4.2 kg, $p<0.001$), body mass index (-4.0 ± 2.1 kg/m², $p<0.001$), waist circumference (-2.7 ± 5.9 , $p<0.001$), and hip circumference (-3.4 ± 4.4 cm, $p<0.001$), and all maintained REE (0.09 ± 2.0 kcal/kg/day, $p=0.008$). CC had the greatest decrease in fat mass (-3.8 ± 4.0 kg, $p<0.001$) and body fat % ($-2.7 \pm 3.4\%$, $p<0.001$) and was the only group that maintained fat-free mass (-0.19 ± 2.00

kg, $p=0.631$). All groups, except WW, had a decrease in resting heart rate (-3.0 ± 9.8 bpm, $p < 0.001$). CC was the only group with a decrease in systolic (-7.6 ± 14.2 , $p=0.002$) and diastolic blood pressure (-3.6 ± 7.3 mmHg, $p=0.045$). CC had the greatest increase in peak aerobic capacity (2.5 ± 2.9 ml/kg/min, $p < 0.001$) and was the only diet group that increased in lower (15.0 ± 21.9 p=0.001) and upper body ($8.7 \pm 12.5\%$ p=0.001) strength. CC trended toward a decrease in total cholesterol to HDL-cholesterol ratio ($-4.9 \pm 11.3\%$, $p=0.053$). Though all diet groups lost weight and had improvements in anthropometrics, CC experienced greater improvements in body composition, blood pressure, peak aerobic capacity, and muscular strength and trended toward improvements in blood lipid ratios.

DEDICATION

To my wonderful husband, Justin, I am grateful to get to walk through life with you. To our beautiful daughter, Elise, your dynamic personality brings us much joy every day, and to our most recent addition, William, you are a sweet little bundle.

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NOMENCLATURE

BMI	Body Mass Index
BP	Blood pressure
C	Control
CC	Curves Complete
DBP	Diastolic blood pressure
DEXA	Dual energy x-ray absorptiometry
FFM	Fat-free mass
FM	Fat mass
GXT	Graded Exercise Test
HR	Heart rate
IR	Insulin Resistance
JC	Jenny Craig
NS	Nutrisystem
REE	Resting energy expenditure
SBP	Systolic blood pressure
TG	Triglycerides
VO ₂ max	Maximal oxygen consumption attained during a graded exercise test

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CHAPTER I

INTRODUCTION AND RATIONALE

Background

The epidemic of obesity is continuing to rise in the United States, and approximately two-thirds of Americans are classified as overweight (a body mass index 25-29.9 kg/m²) or obese (a body mass index of ≥ 30 kg/m²) [1]. Obesity is a chronic disease, and it is rising as a major health problem in the United States [2]. Abdominal obesity specifically, is one of the risk factors for cardiovascular disease around the world [3, 4], and cardiovascular disease is the number one contributing factor of death and disability for women in the United States [5]. Additionally, in 1997, the World Health Organization recognized obesity as a worldwide disease that has an immense impact on public health and stated that overweight or obese individuals have a significantly higher probability of developing numerous chronic disorders such as diabetes, hypertension, and cardiovascular disease [6-11]. Unfortunately, there are no adequate treatment programs for obese individuals. Those who successfully lose weight often regain it within five years [12, 13]. Physical activity is an important contributing factor in losing weight as well as helping to reduce the risk of obesity and numerous other chronic diseases, such as cardiovascular disease, diabetes, depression, and certain cancers [14].

The importance of physical activity is widely accepted as a means to manage weight, and weight-loss interventions that incorporate quality exercise protocols are more effective in yielding long-term weight loss in overweight individuals compared to

interventions that involve dietary changes alone [15-18]. High intensity resistance training improves body composition and muscular strength [19-21]. Inadequate protein intake along with a decrease in physical activity may contribute to sarcopenia, an extreme muscle loss [22-24]. Contracting skeletal muscle can directly stimulate the growth or maintenance of muscle to prevent or treat sarcopenia [25].

Nutritional intake can impact skeletal muscle adaptations and hypertrophy when accompanying resistance training [26]. Nutrients from food can help maintain skeletal muscle and protein synthesis in the presence of resistance training [27]. Layman and colleagues [28] revealed the combined effects of a high protein diet with exercise on improving body composition and reducing total body weight and fat in healthy, overweight and obese women. Similar results were found by Meckling and colleagues [29] as well. An additional study by Cauza et al. [30] examined individuals with Type 2 Diabetes. They compared the effects of both endurance and resistance training and found resistance training helped maintain or increase lean tissue during weight loss. Kerksick and colleagues [31] also conducted a 14-week resistance study with obese individuals and found greater improvements in body composition when a high protein diet was utilized in place of a high carbohydrate diet. This further supported that a high protein diet combined with resistance training may help to promote weight loss, body composition improvements and a decrease in metabolic risk factors. Higher protein diets accompanied with resistance training may also lead to a greater maintenance of fat-free mass and resting energy expenditure.

Nutrient-deficient diets and physical inactivity have both contributed to the increase in obese individuals in the United States and also worldwide [32]. Because of the negative side-effects that are able to result from being overweight or obese, it is important to integrate a weight loss program with proven weight loss strategies and that can affectively lead to changes in body composition and improve markers of fitness and health. Curves® International, Inc., Weight Watchers® International, Inc., Jenny Craig®, Inc., and Nutrisystem® are four widely recognized commercial companies that provide weight management services that are supported by scientifically validated research.

Statement of the Problem

Do different weight-loss approaches implemented by Curves® Complete 90-day Challenge (CC), Weight Watchers® Points Plus (WW), Jenny Craig® (JC), and Nutrisystem® Advance Select™ (NS) promote significantly different results in weight loss, body composition and/or markers of health and fitness in sedentary overweight women?

Purpose

The purpose of this study was to determine whether following the control group (C) or the Curves Complete® 90-day Challenge, Weight Watchers® Points Plus, Jenny Craig®, or Nutrisystem® Advance Select™ weight loss programs for 12-weeks promoted significantly different changes in weight loss, body composition, fitness and health markers in previously sedentary overweight women.

General Study Overview

Four hundred sedentary women were randomized into four different diet and exercise groups or a control group (C). The independent variables were the C group, a Curves group (CC), a Weight Watchers group (WW), a Jenny Craig group (JC), and a Nutrisystem group. The CC group followed the Curves Complete 90-Day Fitness Challenge. The diet included consuming a high protein diet of a 45:30:25 protein to carbohydrate to fat ratio. It consisted of 1,200 kilocalories per day for one week and 1,500 kilocalories per day for the remaining 11 weeks. Subjects in the CC group also participated in a supervised 30-min resistance training circuit training program four days a week, which was interspersed with calisthenics exercises or Zumba dance. CC participants were also encouraged to walk for 30 minutes on the other three days of the week. They were provided with a pedometer to track the number of steps taken each day. 10,000 steps was the encouraged goal by the end of the 12 weeks. Subjects in the WW group followed the Weight Watchers® Points Plus Program. It consisted of food plans based on a points system, and the participants were required to attend a weekly meeting at a local Weight Watchers facility. Exercise recommendations, point tracking methods, and weight reductions strategies were presented and weekly weigh-ins were obtained. Exercise was encouraged but not mandatory. Subjects in the JC program participated in Jenny Craig At Home. They received their meals for the 12 weeks of the study. These participants were required to speak with a JC consultant on the phone once a week to discuss weight loss goals and exercise recommendations. Participants in the NS program followed the Nutrisystem Advance Select Program and also received meals for 12 weeks but were given

the option of calling a NS consultant each week with questions regarding their weight changes and exercise protocol. Online resources were available to both the JC and NS groups. Exercise was encouraged but not mandatory for both the JC and NS groups as well. Those in the C group did not make any changes in diet or exercise for the 12 weeks.

The dependent variables that were measured at 0, 4, 8, and 12 weeks included weight, anthropometric measurements, and scanned body composition. Scanned body composition included total scanned mass, fat mass, fat-free mass, and percent body fat using the Hologic Discovery W QDR series Dual Energy X-ray Absorptiometry (DEXA) system (Watham, MA). Resting Energy Expenditure (REE) was also assessed at 0, 4, 8, and 12 weeks using the Parvo Medics TrueMax 2400 Metabolic Measurement System (Sandy, UT). Serum blood panels, including triglycerides, total cholesterol, HDL-cholesterol, LDL-cholesterol, and total cholesterol to HDL cholesterol ratio, whole blood panels, hormone levels, which included glucose, insulin, glucose to insulin ratio, HOMA, and leptin were also measured at 0, 4, 8, and 12 weeks of intervention. Additional dependent variables measured at 0, 4, 8, and 12 weeks included dietary intake with a 4-day self-reported food log and an Eating Satisfaction Survey, physical activity with a pedometer and an International Physical Activity Questionnaire (IPAQ) and psychosocial questionnaires, including an SF-36 Quality of Life Inventory and a Body Image Questionnaire. Peak oxygen consumption as well as lower and upper body maximal strength and endurance were measured at only 0 and 12 weeks.

Data were analyzed by ANOVA or MANOVA with repeated measures using IBM SPSS for Windows version 20.0 software (Chicago, IL) and were presented as means \pm

standard deviation, unless otherwise noted, and are presented as delta change from baseline or percent change from baseline.

Hypotheses

Ho1: Statistically significant differences will be observed among groups in macronutrient intake.

Ho2: Statistically significant differences will be observed among groups in physical activity levels.

Ho3: Statistically significant differences will be observed among groups in body composition related variables.

Ho4: Statistically significant differences will be observed among groups in variables relating to markers of health.

Ho5: Statistically significant differences will be observed among groups in variables relating to markers of fitness.

Ho6: Statistically significant differences will be observed among groups in blood lipid panels.

Ho7: Statistically significant differences will be observed among groups in hormone levels.

Ho8: Statistically significant differences will be observed among groups in variables relating to psychological evaluations.

Delimitations

The study was conducted under the following guidelines:

1. 200 sedentary women between the ages of 18 and 70 years, with a BMI of 27-50 kg/m² were recruited from Texas A&M University and nearby communities to participate.
2. Eligible participants took part in a familiarization session where they were informed of all testing protocols and requirements. They completed paperwork which included signing an informed consent and were scheduled for testing.
3. Participants did not consume any nutritional supplementation that may have affected muscle mass or metabolism for at least three months prior to the start of the study.
4. Participants did not participate in a planned exercise program for at least three months prior to the start of the study.
5. Participants did not have a weight change of ± 7 pounds within the three months leading up to the study.
6. Participants did not have had a child within 12 months prior to the study, they were not breastfeeding, and they were not planning on becoming pregnant within the upcoming 12 months.
7. Participants did not have any uncontrolled metabolic disorders.
8. Participants refrained from strenuous exercise for 48 hours prior to baseline testing.
9. Participants did not consume any NSAIDs or alcohol 24 hours prior to baseline testing.

Limitations

1. The participants were individuals of the Texas A&M University and nearby communities who responded to radio advertisements as well as school and local paper advertisements. Therefore, the selection process was not truly random. This may have affected the ability to apply the results to the general population.
2. There were inherent limitations of the laboratory equipment that were used for data collection and analysis.
3. The participants completed the Eating Satisfaction Survey, which has not been scientifically proven to be valid or reliable.

Assumptions

1. Participants were fasted for the 12 hours prior to each testing session.
2. Participants had not exercised 48 hours prior to each testing session.
3. Participants did not consume any over the counter medications or alcohol 24 hours prior to each testing session.
4. Participants accurately answered the entrance criteria screening questions as well as the personal and medical history forms.
5. Participants adhered to all of the guidelines during their involvement in the study, including following the assigned diet and exercise protocol.
6. All laboratory equipment was calibrated and functioning properly for all testing sessions.
7. There was consistency by the lab personnel when performing testing sessions.
8. The sample of the population that was used in the study was normally distributed.

9. The variability among the samples was approximately equal.
10. The sample was randomly selected and assigned to the different diet groups.

CHAPTER II

REVIEW OF THE LITERATURE

Introduction

Obesity is a chronic disease, and it is seen as a growing health problem in the United States as well as in many parts of the world [2]. It is often defined as having a body weight that is 10 percent greater than the standard weight or a BMI $\geq 30 \text{ kg/m}^2$ [33]. Obesity-related health risks are augmented when excess fat is most prevalent in the abdominal region and is associated with an increase in visceral fat. The quantity of visceral fat is a better predictor of CVD and metabolic disease than solely the amount of body fat that is present [34-38]. Direct medical expenses related to cardiovascular disease and other obesity related illness, such as hypertension, type 2 diabetes, stroke, asthma, and arthritis is expected to increase as the prevalence of obesity increases [39]. This knowledge underscores the need for effective weight loss strategies to help prevent and reduce obesity and for treatments that help reduce abdominal and therefore visceral fat [40].

Etiology of Obesity

Though the etiology of obesity is not well understood, it is thought that both genetics and environmental factors play a role in its development [41]. Genetics, environmental factors, and psychosocial factors all contribute to body weight, body composition, and storage of energy in the form of triglycerides in adipose tissue [32]. Nutrient-deficient diets and a decrease in energy expenditure are also contributing factors to the rise in overweight and obese individuals through the years. Spiegelman and Flier

[32] addressed that both the quality and quantity of our food sources, as well as the attenuated requirement for physical activity in our society have greatly contributed to the rise in obesity. It was also noted that the genes that contribute to an individual's weight have been present prior to the last few decades. Therefore, it can be concluded that our environment has had a greater impact on the rise of obesity. Given that absorption of nutrients is not impaired, the increase in stored energy is based on the fact that energy intake is exceeding energy output. Physical activity, basal metabolism, and adaptive thermogenesis are all components of energy expenditure. When discussing efforts to balance energy intake versus energy output, a lack of physical activity is a key contributing factor to obesity [41].

Numerous researchers [34-38] have concluded that health risks relating to obesity are increased when there is a greater prevalence of abdominal fat and visceral fat. It is not solely the quantity of whole body fat but the quantity of visceral fat specifically, which is a better predictor of CVD and metabolic disease.

Energy-dense foods, which may also be nutrient-deficient foods, have been linked to the rise in obesity over the past few decades [42-45]. There has been an increased consumption of snacks [46], calorie-filled beverages [47, 48], and fast food [49]. Dietary sugar and fat intake [47, 50], the larger portion sizes that are being consumed [51], as well as the decreased number of nutrient-dense meals that are consumed outside the home [52] have also been studied to evaluate their contribution to the overall weight increase in the U.S.

Prevalence of Obesity

Data on the ratio of height and weight, which can then be used to calculate body mass index (BMI), from the National Health and Nutrition Examination Survey (NHANES) has been utilized since the 1960's to measure obesity prevalence in the United States [53]. Using BMI to define the standards, the percentage of children and adolescents who are overweight has increased significantly in the last 20 years [54, 55]. Seventy percent of children aged 10 to 13 years who are obese will then become obese as an adult [56]. Also, in spite of the more than 54 million Americans who are dieting, there is still a continued epidemic of obesity [53, 55]. The prevalence of overweight and obese individuals continues to rise in the United States (U.S.) with 33.8% of adults obese, according to a national survey in 2007-2008, and about 68% of individuals in the U.S. are overweight and obese combined [57]. From 1980-2002, the prevalence of obesity increased two-fold in adults 20 years of age or older, and the occurrence of overweight children between six and 19 years of age tripled [53, 55, 58]. The rise in the pervasiveness of obesity in both men and women presents a major public health problem which further emphasizes the need to ascertain effective treatments [53, 59].

Implications of Obesity

Atherogenic Abnormalities

Cardiovascular (CVD) disease is the leading cause of death worldwide [60, 61]. More specifically, Coronary Heart Disease (CHD) is the leading cause of death in women in the United State, and dyslipidemia is one of the major risk factors, which is often characterized by inadequate lipid and lipid-cholesterol concentrations [62, 63]. Further,

CVD is the leading cause of mortality in the United States overall, and recent data suggests that between 360,000 and 500,000 women die each year from diseases of the heart [64, 65]. Additionally, in the American Heart Association found the estimated costs of CVD to be more than \$430 billion in 2007 [65]. Treating obesity is of highest importance in the efforts to decrease CVD, in that when obesity is left unaddressed, the risk of cardiovascular disease increases [41]. Further, obesity is associated with hyperinsulinemia, which is an independent risk factor for Coronary Artery Disease (CAD), and is linked to insulin resistance (IR) and atherogenic changes [66]. In combating the risk of developing CVD, physically active individuals have a reduced risk of developing CVD compared with those who are sedentary [67]. A meta-analysis of five different studies by Allison and colleagues [68] found that CVD is more common in those who are obese and physically inactive.

Extensive research has been conducted to assess the impact of exercise on lipid metabolism, and increased physical activity may decrease the risk of CVD by positively changing the lipoprotein profile [69, 70]. The mechanisms by which exercise training influences serum lipoprotein levels are not fully understood, but regular physical activity and exercise training is able to improve lipid and glucose metabolism [70, 71]. Insulin sensitivity is improved with exercise and high density lipoprotein-cholesterol (HDL-C) concentrations can increase in some cases, as well [72]. Also, there is some evidence for a decrease in total cholesterol (TC), triglycerides (TG), and low-density lipoprotein cholesterol (LDL-C) [73-83].

Greene and colleagues [84] conducted a study with 18 physically inactive, overweight and obese men (n=10) and women (n=8). They assessed the effects of acute bouts of exercise and an acute training effect on blood lipids-lipoproteins, and high-sensitivity C-reactive protein (hsCRP). Prior to the exercise training, the subjects participated in an acute exercise session on a treadmill at 70% VO₂max. They then had 12 weeks of endurance exercise training three days per week. During the acute exercise session, participants expended 400 kilocalories and progressed to 500 kilocalories during the 12 weeks. Subjects maintained their normal dietary habits and were either exercising on a land-based treadmill or an aquatic-based treadmill. The acute exercise bout was repeated after the 12 weeks of training. Blood samples were collected right before and 24 hours after the acute exercise sessions. When looking at HDL-C subfractions in women, the HDL_{2b}-C concentration and particle number increased due to exercise training (p<0.05). Exercise training also increased HDL_{2a}-C concentrations as well (p<0.01). Additionally, there was a decrease in HDL₃-C (p<0.01) and HDL mean density (p<0.05) after exercise training. Further, a decrease in LDL₃-C (p<0.05) and particle number (p<0.05) was also seen in women after the exercise training.

Insulin Resistance and Diabetes Mellitus

Along with the severe rise in obesity in the Western and developing countries, is the rise in metabolic complications such as diabetes, dyslipidemia, cardiovascular complications, and cancer. The majority of obesity-related deaths are attributed to secondary metabolic complications [85]. Excessive fatty acid mobilization that is present in abdominal obesity (waist/hip ratio >1.0 for men and >0.85 for women) [86] plays a key

role in many obesity-related metabolic conditions, including insulin resistance. High levels of fatty acid availability and therefore high levels of fatty acid uptake by skeletal muscle can contribute to an increase in intramuscular triglyceride (IMTG) levels [87-89]. There is a strong correlation between IMTG levels and the severity of insulin resistance in that IMTG may indirectly affect the function of insulin, specifically in obese individuals and those with diabetes mellitus [37, 90-94]. In two different studies, it was noted that across ethnic groups and in both genders, there is a strong link between being overweight and possessing diabetes mellitus [95, 96]. An emphasis is placed on central adiposity, the number of years an individual is overweight, as well as the extent to which an individual is overweight as factors which contribute to an increased risk of developing diabetes mellitus [97]. There is further research being conducted to find additional links of how obesity contributes to an increased risk of diabetes, hypertension, dyslipidemia, and the metabolic syndrome [98].

Additional Risk Factors

As noted previously, mortality associated with obesity has been attributed to CVD, diabetes, kidney disease, and various forms of cancer [99, 100], and obese individuals have a greater risk of developing diabetes, dyslipidemia, hypertension, and cardiovascular diseases. These can then lead to an increased risk of mortality [9, 101, 102]. In light of the growing obesity epidemic, it is important for individuals to utilize successful weight-loss treatments.

Individuals who are overweight or obese have a 15 to 48 percent greater risk of experiencing a medically treated injury compared to individuals within a normal weight

range (BMI 18.5-24.9 kg/m²) [103]. There are decreases in immune function, as well as an increased risk of infection [104, 105]. Excess weight has also been associated with sleep apnea, which can pose significant side effects. The excess and unnecessary abdominal pressure on the diaphragm decreases residual lung volume, which can then lead to a reduction in oxygen saturation through the night [97, 106].

An additional risk factor associated with obesity is osteoarthritis. Osteoarthritis is much more prevalent in overweight individuals, and the type of osteoarthritis that is associated with significant excess body weight directly correlates to its development in the knees and ankles [107]. However, in a study by Bray [97], medical ramifications of obesity were evaluated, and it was found that there was also an increase in osteoarthritis in non-weight-bearing joints. This finding leads to the conclusion that there are potential alterations in cartilage and bone metabolism due to the extra weight, which are independent of weight bearing activities.

Nonalcoholic fatty liver disease (NAFLD), which encompasses a variety of liver abnormalities, has also been associated with obesity. Abnormalities associated with NAFLD can include hepatomegaly (swelling of the liver) and elevated liver enzymes. Additional abnormalities include liver histology, which would include steatosis (retention of lipids in the cell), steatohepatitis (accumulation of fat along with inflammation), fibrosis, and cirrhosis [108].

Non-Pharmaceutical Treatments of Obesity

The rate at which obesity is increasing coincides with the rise in individuals who are dieting [109, 110]. More than 54 million individuals in the United States are currently

dieting. Though, the epidemic of obesity continues to grow, with no sign of cessation [53, 55].

Weight loss of 5%-15% of body weight may reduce risk factors associated with obesity as well as provide positive health benefits [111], and diet and exercise are considered useful strategies for weight loss in moderately obese adults [112]. Current treatment programs for reducing obesity have not proven successful long-term, and it has been noted that individuals who have lost weight will regain it within five years [113, 114]. In contrast, it is also beneficial to note, that the efforts proposed to manage the obesity epidemic by way of public health initiatives and drugs have only further underscored their lack of success [85]. Nonetheless, there have been recent studies that have found successful forms of weight loss more long-term [115-117].

Diet Interventions

Caloric Restricted Diets

Diet interventions alone are the most prevalent weight loss method for obesity in spite of the understanding that a lack of physical activity is a contributing factor to obesity [118, 119]. Caloric restricted diets remain as the foundation for obesity reducing strategies. Though, a study conducted with men found that weight loss by way of exercise correlated with a greater attenuation of total body fat, maintenance of lean tissue, and an increase in cardiorespiratory fitness compared to solely diet-based weight loss. Further, exercise even when not accompanied by weight loss is correlated with significant decreases in abdominal obesity [40, 111, 120]. Studies have been conducted which included female subjects, though few have incorporated an exercise protocol that would

expect to yield significant weight loss results [121]. Flechtner-Mors and colleagues [122] conducted a three month weight loss study with a follow-up of four years, where the participants followed the same protocol throughout the time. Sixty females and 15 males completed the intervention. The initial group consisted of 79 females and 21 males (45.2 ± 10.2 years and 33.6 ± 3.6 kg/m²). Patients were randomly assigned to Group A or Group B. Group A consisted of receiving personalized menus of 1200-1500 kcals (19-20%:48-54%:25-34%, PRO:CHO:FAT) including three meals and two snacks. Group B had two of three meals per day replaced with Slim-Fast diet shakes. The third meal was 600-900 kcals with 30-45 g of PRO. The energy intake of each of the diets was the same throughout the study. The first phase was 12 weeks in duration, and the average percent weight loss for Group A and Group B were $1.5 \pm 0.4\%$ and $7.8 \pm 0.5\%$ (mean \pm SEM) respectively. Systolic blood pressure, plasma triacylglycerol, glucose, and insulin concentrations had significantly decreased in Group B, though no changes were seen in Group A. During the second phase of follow-up for 48 months, subjects received the same dietary instructions as during the first phase. At specific times, blood pressure, anthropometric measurements, lab work, and side effects were documented. Generalized estimating equations were used to calculate weight loss [123-125]. There were no differences in percent weight loss between males and females. The first phase was 12 weeks in duration, and the average percent weight loss for Group A and Group B were $-1.5 \pm 0.4\%$ and $-7.8 \pm 0.5\%$ (mean \pm SEM) respectively. Systolic blood pressure, plasma triacylglycerol, glucose, and insulin concentrations had significantly decreased in Group B, though no changes were seen in Group A. Also, at four years, both groups had a

significant decrease in weight compared to baseline ($p < 0.01$). The study promoted the potential benefit of meal replacement as a means for weight-loss and weight-loss maintenance. Additionally, prepackaged meals could help to increase compliance to a diet protocol, because food choices are limited, which could then help to maintain a necessary caloric intake.

Heilbronn et al. [126] organized a longitudinal study involving healthy women with a BMI $> 28 \text{ kg/m}^2$. All the subjects had normal plasma glucose and lipid profiles. The diet component consisted of 1,500 kcals per day and was a low fat diet with only 15% fat. Eighty-three, non-smoking, healthy, obese women (48.0 ± 0.9 years, waist circumference $98.3 \pm 1.0 \text{ cm}$, BMI $33.8 \pm 0.4 \text{ kg/m}^2$, waist/hip ratio 0.83 ± 0.01 cm) completed a 12-week caloric restricted intervention. Participants were not allowed to consume alcohol during the study. Data are represented as mean \pm SEE. Participants recorded their food intake over a three day period, every two weeks. Additionally, every two weeks, participants received dietary counseling and weight checks. Participants reported their food intake, with an average being $1,362.33 \pm 14.34$ kcals/day. The average macronutrient breakdown that was reported was $61.4 \pm 0.3\%$ carbohydrate, $14.2 \pm 0.2\%$ fat, with saturated fat $5.9 \pm 0.1\%$, and $22.8 \pm 0.2\%$ protein. At baseline, the subjects had two consecutive appointments at the testing site and then returned every four weeks until the completion of the 12 week study. Weight was recorded and lab work was performed in a 12-hour fasted state, to measure glucose, serum total cholesterol, HDL cholesterol (HDL-C), and triglyceride concentrations by use of commercially available kits (Roche Diagnostics). LDL-cholesterol (LDL-C) was calculated by using a modified version of the Friedewald

equation [127]. Subjects were also tested for serum C-reactive protein (CRP) concentrations at baseline and after 12 weeks by using an ultrasensitive ELISA (Alpha Diagnostica). Waist and hip measurements were obtained at baseline and after 12 weeks as well. After the 12 weeks, total cholesterol (-10%), LDL-C (-11%), HDL-C (-6%), and triglyceride concentrations (-14%) had significantly decreased. CRP levels were also significantly reduced ($p < 0.001$). CRP was also found to be positively correlated with weight loss ($p = 0.005$) and was highly correlated with BMI after weight loss ($p = 0.001$), as well as fat mass determined by waist circumference ($p = 0.001$) and hip circumference ($p = 0.001$). Triglycerides were the only blood panel measurement highly correlated with CRP concentrations ($p = 0.009$), but CRP levels were also correlated with total cholesterol changes ($p = 0.03$).

High Protein Diets

Farnsworth et al. [128] conducted a study with 14 men and 43 women which evaluated the effects of a high protein and caloric restricted diet. They ranged from ages 20 to 65, possessed a fasting serum insulin concentration of $>12 \mu\text{IU/L}$, a BMI ranging from 27 to 43 kg/m^2 . At the start of the study, most participants were sedentary and were required to maintain pre-testing activity levels. Participants were randomly allocated to either a high protein (HP) diet (30%:40%:30%) PRO:CHO:FAT ratio or a standard amount of protein (SP) diet (15%:55%:30%). Both diets had pre-planned menus, and 60% of the energy intake was provided for the subjects. The study lasted 16 weeks, and subjects were matched according to fasting serum insulin, BMI, age, and sex. The first 12 weeks consisted of 1,500 kcal on average, then there were four weeks of maintaining energy

balance while having the same macronutrient breakdown. Body weight, blood pressure, and venous blood samples were taken after an overnight fast at 0, 4, 8, 12, and 16 weeks. At baseline and 16 weeks, a three hour meal tolerance test was given to measure plasma glucose, serum insulin, and fatty acid concentrations. Body composition was measured using dual energy x-ray absorptiometry. Dietary compliance was measured by a 24-hour urine sample to measure the ratio of urea to creatinine. Further measurements included markers relating to the breakdown of bone and calcium excretion. There was an overall mean weight loss of 7.9 ± 0.5 kg ($p < 0.0001$), but there were not significant differences in weight loss between the HP and SP groups. Total fat mass loss was 6.9 ± 0.4 kg after the 16 week intervention ($p < 0.0001$) but was not different between groups. Men however, lost a greater amount of fat mass compared to the women. There was also a significant reduction in total lean mass 1.2 ± 0.3 kg ($p < 0.0001$). Women experienced a greater loss of lean mass in the SP group than the HP group ($p < 0.02$). Fasting plasma glucose had no significant change from baseline and 16 weeks, but fasting serum insulin decreased by $29 \pm 3.4\%$ at 16 weeks ($p < 0.001$). The HOMA index also decreased $27 \pm 4\%$ at 16 weeks ($p < 0.001$).

Layman and colleagues [28] assessed the effects of diet composition and exercise on body composition and blood lipids during weight loss over a four month period. They hypothesized that an increase in protein and a reduction in carbohydrates along with aerobic exercise and resistance training would yield an additive effect on body fat loss and the maintenance of fat free mass. It was a randomized study with a two diet groups (high protein plus reduced carbohydrates and low protein + high carbohydrates). Both groups

also had an exercise intervention consisting of five days per week of walking and two days per week of resistance training or a control group that had light walking activity. After the 16 weeks of intervention, all groups had a significant weight loss, and body weight changes were greater in the groups that consumed a higher protein and reduced carbohydrate protocol ($p<0.05$). The PRO + EX group had the greatest relative weight loss at 11.2% ($p<0.05$). The interaction of diet and exercise interventions did not yield significant changes in body weight, body composition, hormones, or blood lipids. They also saw increased fat losses with a higher protein diet and exercise group ($p<0.05$). Further, the PRO + EX group did not experience significant changes in lean mass (-0.9%, $p=0.39$), and the CHO group experienced the largest decrease in lean mass (-5.4%, $p<0.001$). Individuals in the PRO and PRO + EX groups had a decrease in relative body fat by -4.3%. Those who did not participate in a supervised exercise program, had a decrease in relative percent body fat by -2.5%.

Furthermore, a study by Kersick et al. [31] compared high carbohydrate and high protein diets with exercise. Participants were allocated into one of six groups: 1) no diet + no exercise control (CON), 2) no diet + exercise (ND), 3) high carbohydrate, high energy diet (HED) + exercise (2,600 kcals; 55:15:30%); 4) very low carbohydrate, high protein (VLCHP) + exercise (1,200; 63:7:30%), 5) low carbohydrate, moderate protein (LCMP) + exercise (1,200; 50:20:30%), or 6) high carbohydrate, low protein (HCLP) + exercise group (1,200; 55:15:30%). Participants were sedentary, obese females (38.5 ± 8.5 yrs, 164.2 ± 6.7 cm, 94.2 ± 18.8 kg, 34.9 ± 6.4 kg/m², $43.8 \pm 4.2\%$ body fat). There were 161 subjects who participated in the 14 week study. Dependent variables included

anthropometric measurements, body composition, cardiovascular and muscular fitness, serum and whole blood, hormonal changes, and psychosocial parameters. The VLCHP, LCMP, and HCLP groups all restricted caloric intake combined with exercise and had similar significant reductions in DEXA fat-free mass. There were also similar changes in DEXA fat mass in the same groups after both 10 weeks and 14 weeks which led to an overall reduction in DEXA percent body fat. Decreases in DEXA fat measurements were significantly greater in the VLCHP group after 14 weeks compared to the HED, ND, and CON groups ($p<0.05$).

Exercise Interventions

Aerobic Exercise

Physical activity has been encouraged as a means to reduce the risk of obesity. It has also been seen to help reduce the risk of several chronic diseases that are linked to obesity, such as cardiovascular disease, diabetes, depression, and certain types of cancer [14]. Physical activity has also been attributed as a successful intervention for weight control, and weight-loss interventions that include exercise are more effective in helping maintain weight loss long-term in overweight individuals compared to interventions that focus solely on diet changes [15-18].

Greene et al. [129] had 57 physically inactive, overweight, and obese men ($n=25$) and women ($n=32$) with baseline demographics of: 44 ± 2 yr, 90.5 ± 2.4 kg, 30.5 ± 0.7 kg/m², $39.5\%\pm 1.2\%$, and 27.5 ± 0.7 ml/kg/min. Subjects were randomly assigned to either LTM (land treadmill) or UTM (underwater treadmill) training. Participants maintained their typical dietary habits throughout the study. Exercise training consisted of three sessions

per week during the 12 weeks. All subjects had the same caloric expenditure, and the intensity of the exercise was decided from the maximal graded exercise test. VO_2max was increased in both the UTM and LTM group ($p<0.0001$). Body mass ($p<0.001$), BMI ($p<0.0001$), waist circumference ($p<0.0001$), hip circumference ($p<0.001$), and waist-to-hip ratio ($p<0.05$) were all significantly lower in both groups after 12 weeks of training.

Kraus and colleagues [130] also conducted a study with 111 men and women who had mild dyslipidemia. They were randomly assigned to one of three exercise groups for eight months or to a control group for only six months. The exercise groups were: 1) high-amount-high intensity exercise (a caloric equivalent to jogging about 20 miles per week for a 90 kg individual at 65%-80% of VO_2max), 2) low-amount-high-intensity (a caloric equivalent to jogging 12 miles per week at 65%-80% of VO_2max), and 3) low-amount-moderate-intensity (a caloric equivalent to jogging 12 miles at 40%-55% of VO_2max). The subjects in the high-amount-high-intensity group were required to expend 23 kcals per kilogram of body weight each week. Whereas, subjects in the two different low-amount groups needed to expend 14 kcals per kilogram of body weight each week. All groups used cycle ergometers, treadmills, and elliptical trainers as sources of exercise. Participants also wore heart rate monitors (Polar Electro) while exercising. Subjects were instructed to maintain their body weight through the duration of the study. However, both high-amount-high-intensity and low-amount-moderate-intensity groups lost significantly more weight than those in the control group. Additionally, the high-amount-high-intensity and low-amount-high-intensity groups had significant increases in peak oxygen consumption compared to the control group ($p<0.001$). These findings revealed that the

intensity of the exercise was of greater importance than the amount of exercise in regards to improving fitness levels.

Additionally, Kodama and colleagues [131] conducted a meta-analysis of research from 1966 to 2005. The studies were randomized controlled studies conducted with adults >20 years of age. They all involved aerobic training, HDL-cholesterol measurements at baseline and at the end of the study, at least eight weeks of training, and included a non-exercise control group. The aerobic exercise was defined as rhythmic and repeated movements of the same large-muscle groups for at least 15 minutes. There were 21 trials that had an estimated energy expenditure greater than 900 kcal per week, and a significant ($p<0.001$) mean difference in HDL cholesterol change (MDHC) was seen in the exercise groups and not in the non-exercise controls. Further, in 25 trials where the total weekly exercise length was greater than 120 minutes, there was also a significant ($p<0.001$) MDHC seen. Univariate analysis revealed that exercise duration was the greatest predictor of MDHC and that the MDHC was not significantly different when exercise bouts were only 30-minutes or less in duration.

It has been noted that a large contributing factor for why individuals stop exercising is due to injury [132]. In a longitudinal study done by Janney and Jakicic [133], 397 sedentary adults with a BMI between 25 and 40 kg/m² participated in an 18-month study which emphasized exercise to either help promote weight loss or prevent further weight gain. The effects of exercise and BMI on the frequency of injuries or illnesses relating to exercise were observed. It was concluded that overweight and obese adults who were prescribed an exercise protocol did not have a greater risk of injury compared to the

controls. However, the onset of injury or illness was attributed to body mass index. The value of regular aerobic exercise in reducing the risk of CVD has been well accepted, and the effects of exercise as both primary and secondary treatment for CVD are well known [76, 134-141].

Resistance Exercise

According to the American College of Sports Medicine [142] and the American Heart Association [143], healthy adults are recommended to exercise at moderate intensity for at least 30-minutes a day on five days of the week or at vigorous intensity for at least 20 minutes a day on three days of the week. Sarcopenia is the process in which there is a wasting of skeletal muscle mass, often correlating with aging [144]. Inadequate protein intake and low levels of physical activity are two factors which contribute to sarcopenia, or muscle wasting [22-24]. Having an adequate nutrient intake impacts skeletal muscle adaptations and hypertrophy in conjunction with resistance training [26]. When skeletal muscle contracts, it stimulates the growth or maintenance to prevent or treat sarcopenia and osteoporosis that is associated with aging [25]. In a study by Andrews et al. [145], individuals between 60-69 years of age were involved in varying intakes of protein combined with resistance training for 12 weeks. Participants also consumed a post-exercise drink with 0.4g/kg lean mass protein. Significant increases in lean mass (1.1 ± 1.5 kg) were noted, and the variability in daily protein intake was not correlated with changes in lean mass ($p > 0.05$).

Prabhakaran and colleagues [70] looked at resistance training on lipid profile and body fat percentage. It was a 14 week study where 30 healthy, sedentary, non-smoking

premenopausal women were randomly assigned to either a resistance exercise training group or a sedentary control group. One week prior to participating, height/weight measurements, skinfold measurements, 1-RM, and a blood sample were obtained. Subjects also kept a three days diet record. Subjects were instructed to maintain their current dietary intake. The resistance exercise consisted of 45-50 minute sessions three times per week at 85% 1RM. Those in the control group were not allowed to participate in any structured exercise or activities. Exercises included bench press, leg press, leg extension, leg curl, and latissimus dorsi pull by way of a circuit training machine. Bicep curls, military press, and triceps extensions were performed with free weights. A new 1RM was estimated at the end of each week. There was a nine percent decrease in total cholesterol ($p>0.05$) and a 14.3% decrease in total cholesterol to HDL-cholesterol (HDL-C) ratio ($p>0.05$). Results also trended toward a decrease in LDL to HDL-cholesterol ratio in the resistance trained group versus the control group ($p=0.057$). Body mass did not change significantly in either group, but body fat percentage significantly decreased in the resistance training group ($p<0.05$) but not in the control group. Further, resistance training did not significantly affect triglycerides or HDL-C, but there was a significant correlation between the percent change in estimated body fat and the percent change of HDL-C ($p=0.0034$). Additionally, there was a trend toward significance in the correlation between body fat percent change and the percent change in total cholesterol ($p=0.08$) for all subjects as well as a significant association between body fat percent change and the percent change in HDL-C ($p=0.05$). There were significant increases in estimated 1RM ($p<0.05$) in all eight of the strength exercises. Further, there was a significant correlation

between the percent change in total cholesterol and the percent change in total strength for all subjects ($p=0.0026$).

Aerobic Plus Resistance Exercise

Park and colleagues [146] conducted a study with 30 apparently healthy, obese women, 40 to 45 years of age, who were not taking regular medications. Subjects were placed into one of three groups: 1) an aerobic training group ($n=10$), 2) a combined training group ($n=10$), or 3) a control group ($n=10$). Height, weight, resting blood pressure, and body mass index (BMI) were measured and calculated respectively. Percent body fat and lean body mass were also measured by Inbody3.0. All participants performed a maximum treadmill test following Bruce protocol guidelines. Indications for stopping the test followed the American College of Sports Medicine (2000) [147]. Aerobic training consisted of 60 minutes per day, six days per week at 60% to 70% of HRmax for the first 12 weeks of the study, involving side by side, step touch, lunge, v-step, grapevine, pivot turn, cha cha, mambo rock, diamond step, single hamstring walking heel touch, sit-up, and push-up. During weeks 13-24, resistance was at 60-70% of HRmax, involving fast walking, turn round, heel side, knee-up, scissors double, hop and jump, jumping jack, side kick, full turn, and double kick. Resistance training was completed 60 minutes a day at 60% of 1RM during 1-12 weeks. For weeks 13-24, it was at 70% of 1RM. The combined training group had resistance training 3 days per week and aerobic training 3 days a week, alternating from resistance training. Relative $VO_2\text{max}$ was significantly increased in both the aerobic and combined training groups ($p<0.01$). In the control group, there was a significant increase in percent body fat after the 24 weeks. Additionally, weight and body

fat percentage were significantly reduced in both of the training groups compared with the control group. Lean body mass was unchanged in the aerobic trained group. In contrast, in the combined training group, lean body mass was increased ($p<0.05$). In both the aerobic training ($p<0.05$) and the combined training group ($p<0.01$), subcutaneous fat volume was decreased. Additionally, visceral fat volume, as well as visceral fat volume/subcutaneous fat volume ratio were decreased in the aerobic and combined training group ($p<0.01$). Total cholesterol, LDL-cholesterol, and triglycerides significantly decreased ($p<0.01$). Additionally, HDL-cholesterol was increased in both training groups ($p<0.01$).

Diet and Exercise Interventions

A decrease in body weight in obese individuals of five percent to 15 percent is able to reduce risk factors that are associated with obesity [111]. In a meta-analysis conducted by Miller et al. [15], subjects in all the acquired studies were randomized into three different groups, a diet group (D), an exercise only group (E), and a diet plus exercise group (DE). Subjects were 18 to 68 years of age and 26% of the sample populations were male and 46% were female. Criteria also required participants to be overweight, which was defined either by the original author, as $\geq 120\%$ of ideal bodyweight, a BMI ≥ 27 kg/m², or body fat $\geq 30\%$. The diet intervention consisted of caloric restriction or a decreased energy intake, and the exercise group only had aerobic exercise. The aerobic exercise protocol consisted of 14-120 min in duration with a frequency of two to seven days per week. The main focus of the meta-analysis was to determine the effects of D, E, or DE on energy balance leading to changes in body weight and body composition. There

was a significant difference between the D and DE groups versus the E group in a decrease in body weight, fat, body fat percentage, and BMI. Though, there were no significant differences observed between groups D and DE. However, the studies that involved exercise alone, had subjects who were younger, lower baseline weights, lower baseline BMI values, and lower baseline body fat percentages compared to those in the D and DE groups. When evaluating body composition changes between the three groups, those in the E group had less weight loss, fat loss, a smaller decrease in body fat percentage, a smaller decrease in BMI, and a smaller percentage of initial weight loss. In contrast though, at the one year follow-up, no differences were observed between the three groups in weight loss maintenance. There were seven E studies that had a one year follow-up program, and the data showed that those subjects maintained 70% of their initial weight loss compared to 73% in the D and DE groups.

A meta-analysis by Curioni and Lourenco [112] compared nine different previous studies from both the United States and Finland. The sample size of the studies ranged from 40 to 127 participants who were between the ages of 21 and 65 years. Three of the studies that were compared included only women, one study had only men, and two of the studies had both men and women. The length of involvement for the participants ranged from 10 to 52 weeks. There were also follow-ups that ranged from 12 to 24 months. Participants met (primarily in small groups) once a week in all the studies except for one. The baseline weight of the subjects ranged from 83.5 kg to 106 kg. Diets involved any form of caloric restriction, and the exercise was any form that was able to be quantified. Those individuals who were in a diet and exercise group had an average weight loss of

about 20% greater than those in a diet group alone. ($p=0.063$). After a one year follow-up, maintenance of weight loss was also shown to be 20% greater in the diet and exercise groups compared to just diet alone ($p=0.058$).

Ross et al. [148] conducted a randomized controlled study in Canada with obese and insulin resistant women. Women were premenopausal, BMI >27 kg/m², waist circumference >88 cm, weight stable (± 2 kg) for six months, nonsmokers, consumed an average of <2 alcoholic drinks per day, sedentary (no structured physical activity for the year prior to the study), and were taking no medications of any kind. Subjects also were tested prior to participation for a normal glucose tolerance and plasma lipid profile. Women were randomly assigned to one of four groups: 1) diet weight loss, 2) exercise weight loss, 3) exercise without weight loss, and 4) control group. Resting energy expenditure was obtained at the start of the study and multiplied by 1.5 to determine the estimated energy requirements for each individual. Subjects were randomly allocated to either a diet weight loss group (reducing isocaloric diet by 500 kcal/day, $n=15$), exercise weight loss (maintained isocaloric diet combined with expending 500 kcal/day, $n=17$), exercise without weight loss (consumed calories to compensate for expending 500 kcal/day, $n=12$), or a weight-stable control ($n=10$) for 10 weeks of intervention. An initial four to five weeks of an isocaloric diet was maintained prior to the 10 week phase. The percent macronutrient breakdown was 50%-60% carbohydrate, 15%-20% protein, and 20%-30% fat throughout the 14 weeks. Exercise consisted of daily walking or jogging on a treadmill at about 80% of maximal heart rate until 500 kcal were expended. Waist circumference changes were greater in the weight loss groups compared to the control

($p < 0.001$) but not significantly different from each other ($p > 0.05$). The average decrease in waist circumference in the diet weight loss and exercise weight loss groups were -4.1 ± 2.4 and -6.5 ± 2.6 cm respectively. Further, there was a significant decrease in total fat ($p < 0.001$) in both weight loss groups, and it was greater in the exercise weight loss group (-2.6 kg) compared to the diet weight loss group ($p < 0.001$). Average weight decrease was -5.2 ± 1.2 in the diet weight loss group and -6.1 ± 1.2 kg in the exercise weight loss group.

Commercial Weight Loss Interventions

In conjunction with the staggering rise in the pervasiveness of obesity, efforts have increased in order to develop effective methods to prevent weight gain. However, about 68% of adults in the United States are currently overweight or obese, and it is imperative for effective treatment programs to be created for this population [57, 149]. There are a growing number of commercial diets and programs on the market which promote effective weight loss strategies. Heshka and colleagues [150] proposed that commercial weight loss programs are able to yield a level of weight loss that is equal to or surpasses interventions from traditional counseling or medicine. However, there are few studies that have evaluated commercial weight loss programs in depth. As a result, there is little known about the results of that an overweight or obese individual would experience in one of the programs. There is little scientific data available for individuals to use to make a valid assessment about the current diet services and programs offered, which was noted in a study by Wing [149].

A qualitative study conducted in Victoria, Australia by Thomas and colleagues [151] utilized open-ended interviews with 76 people who were currently obese (BMI of \geq

30 kg/m²). The purpose of the study was to attempt to interact with individuals who were obese and had attempted to lose weight, to understand their perspective on dieting, and to have a better understanding of what they believe would be beneficial to them in their attempt to lose weight. Data were analyzed by using a constant, comparative method to develop and validate each category. Data were then interpreted within team meetings as well as by allowing the participants the opportunity to give their perspective on the findings of the study. Participants strongly favored commercial diets as a means to lose weight and participating in physical activity was not highly favored by many. The obese individuals were often introduced to the various weight loss strategies by friends and family members. It was also noted that those who participated in their weight loss intervention with their peers had a greater sense of acceptance and support. The individuals who were unable to adhere to the diet protocol believed it was their own fault that they were not able to lose weight. Even though participating in the diet interventions did not lead to a sustained weight-loss, two thirds of participants felt as though they were effective. It was concluded that very few individuals with obesity are provided with long-term supervision or support with effective ways to lose weight, though many have received short-term advice. Understanding the impact that social networks may have in helping with weight loss may be of importance when participants are involved in physical activity.

Curves Research

A study by Kerkick et al. [31], previously discussed, was conducted to determine the safety and efficacy of following the Curves diet when altering the ratio of carbohydrate and protein, along with following the Curves exercise protocol. Kerkick and colleagues

[152] then conducted an additional study which evaluated the impact of various macronutrients and caloric intakes combined with regular exercise, on metabolic and physiological changes related to weight loss. Both studies worked with obese women and consisted of low-energy diets in conjunction with popular exercise programs. Participants were randomized into one of six groups with various diet and exercise protocols and were randomized according to age and body mass. In the first phase of the study (Phase I) participants followed one of four diet and exercise protocols based on energy intake, carbohydrate, protein, and fat percentages for one week: 1) high energy, high carbohydrate, low protein (2,600 kcal; 55:15:30%; HED), 2) low carbohydrate, high protein (1,200 kcal; 7:63:30%, VLCHP), 3) low carbohydrate, moderate protein (1,200 kcal; 20:50:30%; LCMP), or 4) high carbohydrate, low protein (1,200 kcal; 55:15:30%; HCLP). The second phase (Phase II) lasted nine weeks, and the caloric intake was set at 1,600 kcal for the VLCHP and HCLP groups, and their ratios were changed to 15:55:30%. The HED group breakdown changed to 2,600; 40:30:30%. The last phase (Phase III) continued for four weeks, and during this time all participants followed the same protocol of 2,600 kcal; 55:15:30%). Participants also weighed in each day. If there was a weight gain of three pounds, subjects returned to following Phase I until the weight was lost. Testing sessions were conducted at baseline, 1, 10, and 14 weeks. Changes in waist circumference were improved in all the groups that had both resistance exercise and energy restriction and were significantly different over time and compared to the control group. Body mass and percent fat also improved in the groups with resistance exercise and caloric restriction. With a significant main effect over time ($p < 0.001$) and a group x

time interaction for fat-free mass ($p < 0.05$). Those in the HCLP group were the only ones to have a significant decrease in fat-free mass compared to those in the control but not compared to the other groups. These findings could further support the positive effects of higher protein in maintaining fat-free mass when caloric restriction is present. Diets low in carbohydrates may yield greater weight-loss due to a greater sense of satiety from higher protein amounts [153], and there is a growing interest in studying diets that are high in protein and possess a moderate amount of carbohydrate and fat [154-156].

Weight Watchers Research

Numerous studies have evaluated the efficacy and effectiveness of Weight Watchers [150, 157-163] with weight loss as a significant result for the participants in short-term and long-term protocols [150, 157-159].

In a study by Dansinger and colleagues [164], four popular commercial diets were compared to evaluate differences in weight loss and heart disease risk reduction. The Atkins diet, the Zone diet, Weight Watchers, and the Ornish diet were the four commercial diets that were assessed. Participants had a BMI ranging from 27 to 42 kg/m² and had at least one of the cardiac risk factors listed: fasting glucose of greater than or equal to 110 mg/dL, total cholesterol of greater than or equal to 200 mg/dL, low-density lipoprotein (LDL) cholesterol of greater than or equal to 130 mg/dL, high-density lipoprotein (HDL) cholesterol of 40 mg/dL or less, triglycerides of greater than or equal to 150 mg/dL, systolic blood pressure of greater than or equal to 145 mmHg, diastolic blood pressure of greater than or equal to 90 mmHg, or were using oral medications to treat hypertension, type II diabetes, or dyslipidemia. Results were assessed at baseline and 1, 2, 6, and 12

months. All participants were instructed to take a multivitamin each day, participate in 60 minutes of exercise each week, and to avoid commercial support services. Participants followed the diets for two months, and then followed them according to their interest level. A three day diet record was analyzed at baseline and 1, 2, 6, and 12 months. Phone calls were also made to the participants each month to assess personal perspective of adherence to the diet based on a 10 point scale. Body weight, waist circumference, and resting blood pressure were measured. Lab work was also conducted after an overnight fast, measuring total cholesterol, HDL-C, triglycerides, glucose, insulin, CRP, and creatinine levels. LDL-C was also measure using the Friedewald formula [127]. Urine sample were also obtained. All four of the diets experienced significant weight loss after one year, but data was not significant between groups. In all the groups, about 25% of the participants maintained a weight loss of more than five percent of their initial body weight, and about 10% lost more than 10% of their body weight. Waist circumference was also strongly correlated with weight loss.

Another study by Morgan and colleagues [165] also compared Weight Watchers Pure Points program, which was an energy-controlled low-fat healthy eating diet, to three other commercial weight-loss programs and their effects on lipid-based cardiovascular risk factors. The three other commercial-diet programs were The Slim-Fast Plan, which was a low-fat meal replacement approach, Dr. Atkins' New Diet Revolution, a low-carbohydrate diet, and the Rosemary Conley's 'Eat Yourself Slim' Diet and Fitness Plan, which was an energy-controlled low-fat healthy eating diet with one weekly group exercise class. Subjects ranged in age from 18-65 and had a BMI between 27-40 kg/m².

Weight, blood pressure, and waist circumference were measured every four weeks, and fasting blood samples were obtained at baseline, eight weeks, and 24 weeks. There was a significant weight loss after the six month intervention in all four diet groups ($p < 0.001$). After six months, LDL-cholesterol concentrations decreased in the Weight Watchers, Slim-Fast, and Rosemary Conley groups. Plasma triacylglyceride concentrations also decreased in the Atkins, Weight Watchers, and Rosemary Conley groups. Further, HDL-cholesterol decreased significantly in all groups, except the Atkins group. Additionally, plasma insulin decreased in all four diet groups.

Heshka and colleagues [150] compared self-help diets to commercial diets, and it was found that commercial diets did provide greater weight loss compared to the self-help diets. The study was a randomized, parallel-group, 2-year trial that was conducted at six clinical centers in the United States between January 1998 and January 2001. Men and women participated were between 18-65 years and had a BMI from 27-40 kg/m². Participants were also allowed to have health problems where weight reductions was a medically accepted therapy. Participants in the self-help group received consultations with a dietitian for 20 minutes at baseline and at week 12. Those in the commercial diet group had Weight Watchers membership paid for them. The design of the program was to lose up to 0.9 kg/wk. In the commercial group, change in weight at one year ranged from -28 to +12 kg and from -23 to +21 kg after year two. In the self-help group, the range after one year was -26 to +15 kg and -26 to +30 after two years. Weight was significantly lower than baseline in the commercial group and the total weight loss was greater compared to the self-help group. Until week 52, weight loss was significantly lower in the self-help

group. When assessing BMI changes after one year, 56% of those in the commercial group were one BMI unit less than at baseline, and 52% were after two years. In the self-help group, 31% were after one year, and 29% were one BMI unit lower compared to baseline. Significant differences were seen in waist circumference decreases at both one and two years. Significant differences were also seen between commercial and the self-help group in the average amount of fat loss that was maintained through the last 18 months of the study.

Jenny Craig Research

Rock et al. [166] conducted an initial study assessing the efficacy of the Jenny Craig program where 70 female participants followed either the Jenny Craig program or the usual care protocol. Those in Jenny Craig attended weekly meetings at a Jenny Craig center. They received all their food free of charge and the diet was 1,200-2,000 kcal/day of prepackaged meals. Physical activity was encouraged for 30-minutes per day on five or more days of the week. The individuals in the usual care control group were given consultation meetings at baseline and 16 weeks with a dietitian. Their goal was to have a weight loss of 10% over a 6 month period with a 500 to 1,000 kcal/d deficit. Data collection of anthropometrics, blood work, questionnaires, and a step test occurred at baseline and 6 and 12 months. After 6 months, an average decrease in weight of -7.2 kg, in waist circumference of -7.1 cm, and hip circumference of -5.7 cm ($p < 0.01$ for all three variables). At 12 months, those in the Jenny Craig program lost an average of 7.3 kg, 9.0 cm in waist circumference, and 6.7 cm in hip circumference compared with the usual group participants who lost only 0.7 kg, 0.2 cm from the waist, and 0.3 cm from the hips.

Rock and colleagues [167] conducted an additional study where 442 overweight and obese women (BMI 25-40 kg/m², 18-69 years of age) were randomized into two weight-loss groups and were monitored over a two year period. The first group participated in an in-person center-based program and the second group was telephone-based one-on-one weight loss counseling. Menus were set and prepackaged food items were provided during the initial weight-loss phase, and physical activity was encouraged. The meals involved a decrease in caloric intake while still maintaining adequate nutrition. The prepackaged prepared food items consisted of a low-fat (20%-30%), reduced caloric intake (1,200-2,000 kcal/day) and were free to the participants. The meals also had an increase in vegetables and fruits to help decrease the energy density of the meals. As the study progressed, participants shifted to a meal plan that consisted mainly of foods that were not provided by the commercial program. However, one prepackaged meal was still allotted each day during the weight loss maintenance period. All of the prepackaged meals and counselors were provided either in person or over the phone by Jenny Craig®. The weight loss counseling sessions were with a dietitian, and an energy intake of a 500-1,000 kcal/d deficit was prescribed in order to obtain a 10% weight loss over a six month period [168]. The physical activity component of the program consisted of 30 minutes of physical activity on five or more days of the week. Those involved in the center-based program lost an average of 10.9% of their initial weight after one year of involvement. Also, weight loss between 12 and 24 months was 27% in both of the intervention groups compared to 17% in the usual care group (p = 0.003). They also maintained 7.9% of their weight loss on average, after 24 months of involvement. Total cholesterol to LDL-cholesterol and

leptin levels also showed trending improvements. There were improvements in cardiopulmonary fitness, which was assessed by a step-test. After the 24 month study, 62% of the center-based participants and 56% of the telephone-based participants had a weight loss of at least 5% versus only 29% of those who received usual care. Additionally, more than 37% of the center-based and telephone-based intervention groups versus 16% of the usual care had a weight loss of at least 10% of baseline weight, by the end of the study.

Nutrisystem Research

A study conducted by Foster et al. [169] included 69 participants who followed a Nutrisystem diet. After 12 weeks of intervention, those who followed the Nutrisystem diet had a significantly greater reduction in body weight compared to those who were in the group that provided diabetes support and education (-7.1% vs. 0.4%). After 24 months of intervention, weight loss was maintained in the Nutrisystem group. Little research has been conducted which has looked at the efficacy of the Nutrisystem program. Though, there is research that evaluates low glycemic index diet protocols, which is a component of Nutrisystem meals [170]. Larsen and colleagues [171] evaluated weight loss maintenance by comparing groups with either a high or low protein intake as well as a high or low glycemic index. Diets that involve a low glycemic index may be an asset for improving body weight and body composition [171] and may positively impact certain risk factors in overweight individuals [172, 173].

Comparative Studies

Analyzing the comparative effectiveness in a study evaluates the impact of different options that are available for treating a given condition [174]. Wadden and colleagues [175] assessed a number of studies on commercial weight loss programs, including Weight Watchers, Jenny Craig, and Nutrisystem. It was determined that commercial weight loss programs in general may provide success for overweight and obese individuals who are unable to obtain common lifestyle modifications. Nonetheless, the cost of the programs may be a limitation for whether or not an individuals would be able to participate. In this study, we compared similar commercial weight-loss programs. The cost to benefit ratio was assessed. A benefit of running a comparative study is potentially being able to disprove common assumptions about a given treatment [174].

Summary of Weight Loss Benefits

The negative risk factors associated with overweight and obese are potentially reversible [176]. Weight loss helps to improve blood pressure, lipid levels, as well as glucose tolerance among overweight individuals who have hypertension, dyslipidemia, and diabetes [177-183]. Additionally, in hypertensive and diabetic patients, weight loss has led to a reduction in medication usage [184, 185]. However, there are advantages and disadvantages of various diet and exercise interventions in various populations. Analyzing the comparative effectiveness in a study evaluates the impact of different options that are available for treating a given condition [174]. The purpose of the present investigation is to compare the effectiveness of commercially available weight loss programs that involve different diet and exercise interventions on weight, resting energy expenditure, total mass,

fat mass, fat-free mass, body fat percentage, triglycerides, total cholesterol, HDL-cholesterol, LDL-cholesterol, glucose, insulin, leptin, peak aerobic capacity, and isotonic muscular strength and endurance in sedentary, overweight women.

CHAPTER III

METHODS*

Participants

One hundred thirty-three women (47.2 ± 11.3 yrs, 161.9 ± 6.7 cm, 92.8 ± 14.6 kg, 35.5 ± 5.6 kg/m², $45.8 \pm 4.5\%$ body fat) were randomized into one of five groups. The institutional review board (IRB) approved the protocol prior to initiating the study #2010--0813. Initial screening was obtained via telephone. In order to be eligible to attend a familiarization session, subjects were not allowed to have participated in a planned exercise program in the three months prior to the study, which included not having participated in an organized exercise program for more than 30 minutes a day on at least three days of the week. The participants gave a self-reported weight and were not allowed to have a weight change of either gaining or losing seven pounds in the three months prior to starting the study. Additionally, they were not allowed to participate if they were currently pregnant or nursing, if they had a child within the last 12 months, or if they were planning on having a child within the upcoming 12 months. Subjects were also not allowed to participate if they had any uncontrolled metabolic disorders such as electrolyte abnormalities, heart disease, arrhythmias, diabetes, thyroid disease, hypogonadism, a history of hypertension, hepatorenal disease, musculoskeletal disease, autoimmune

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disease, or neurological disease. If participants were taking any thyroid, hyperlipidemic, hypoglycemic, anti-hypertensive, or androgenic medications, the medications needed to have stayed the same within the three months prior to the study. Additionally, within the three months prior to testing, if the participants had taken ergogenic levels of nutritional supplements that could have affected muscle mass (e.g. creatine, HMB), anabolic/catabolic hormone levels (androstenedione, DHEA, etc.), or weight loss (e.g. ephedra, thermogenics, etc.), they were not eligible to participate. The participants needed to be willing to participate in an exercise program, and they also were required to have a body mass index between 27 and 50 kg/m². Subjects who had a controlled medical condition were required to have a physician clearance form (Appendix D) completed and signed by their physician prior to participating in the study. Subjects who met the eligibility criteria through a phone screening were then allowed to attend a familiarization session where they were informed of the study requirements and signed an informed consent statement in compliance with the Human Subjects Guidelines of Texas A&M University and the American College of Sports Medicine.

Study Site

All testing sessions took place in the Exercise and Sport Nutrition Laboratory, in the Department of Health and Kinesiology at Texas A&M University in College Station, Texas.

Experimental Design

The overview of the research design and timeline for all testing sessions is displayed in Table 1. After attending a familiarization session, if an individual was still

eligible for the study, they were randomly assigned to one of the four diet groups or the control group. The subjects participated in a baseline testing session followed by three additional testing sessions, each four weeks apart. Resting testing measurements as well as fasting lab work were conducted at all four testing sessions. Exercise testing procedures were conducted only at baseline and the final testing session. A post-study questionnaire was administered at the completion of the study as well (Appendix I).

Independent and Dependent Variables

The independent variables in the study included the diet intervention, including Curves Complete® 90-day Challenge (CC), Weight Watchers® Points Plus (WW), Jenny Craig® At Home (JC) or Nutrisystem® Advance Select™ (NS) as well as the exercise protocol of each commercial weight loss program. Dependent variables included weight, resting energy expenditure, body composition, resting heart rate, resting blood pressure, waist and hip anthropometric measurements, one repetition maximum (1RM), 80% 1RM endurance, peak aerobic capacity, fasting serum and whole blood profiles (total cholesterol, triglycerides, HDL-cholesterol, LDL-cholesterol, glucose, insulin, and leptin). Estimated dietary energy intake was evaluated by a four-day diet record (Food Processor Nutrition Analysis Software Version 10.12.0 ESHA Nutrition Research) (Appendix F) and an eating satisfaction survey (Appendix E). The participants' estimated weekly physical activity was monitored by a physical activity log (Appendix G), the International Physical Activity Questionnaire, and those in the CC group were also provided with a pedometer. Psychosocial evaluations were assessed by the standardized quality of life questionnaire (SF-36) and a body image questionnaire (BIQ).

Familiarization Session

Individuals who were interested in the study were screened by phone to determine whether they were eligible to attend a familiarization session. During the familiarization session the participants completed a personal history (Appendix B) and medical history (Appendix C) form and also signed the consent form (Appendix A). They received written and verbal explanations of the study protocol and design, testing procedures, including the lab work, and equipment that was used during their participation in the 12-week study. The participants were given instruction on how to accurately record dietary intake and physical activity throughout the 12 weeks. A tour of the lab was also given in order to show each component of a testing session. Height and weight of each participant were recorded, and the completed forms were reviewed. Participants who had controlled metabolic disorders were required to obtain medical clearance from their physician prior to participating in the study. They needed to have their physician sign a Physician Clearance Form (Appendix D) provided by the lab. After a thorough explanation of the study was provided, if participants were still eligible and interested in participating in the study, they were scheduled for their baseline testing session and randomized into one of the five groups.

General Methods and Design

Pre-Testing Guidelines

Prior to each testing session, participants were asked to record four days of their dietary intake, which included three weekdays and one weekend day. They also recorded their physical activity seven days prior to baseline testing. Participants were asked to not make any changes to their regular diet and exercise patterns prior to starting the study and

Table 1: Overview of research design and testing schedule.

Familiarization and Entry (T0)	Baseline (T1)	4 weeks (T2)	8 weeks (T3)	12 weeks (T4)
Phone interview	Psychosocial Questionnaires: SF-36 QOL ^a BIQ ^b	Psychosocial Questionnaires: SF-36 QOL ^a BIQ ^b	Psychosocial Questionnaires: SF-36 QOL ^a BIQ ^b	Psychosocial Questionnaires: SF-36 QOL ^a BIQ ^b
Familiarization session				
General medical exam by a physician to determine qualifications to participate in study.	Review Food Logs Eating Satisfaction Survey	Review Food Logs Eating Satisfaction Survey	Review Food Logs Eating Satisfaction Survey	Review Food Logs Eating Satisfaction Survey
Randomization into diet programs or control group	Review Activity Logs	Review Activity Logs	Review Activity Logs	Review Activity Logs
	Fasting Blood Samples	Fasting Blood Samples	Fasting Blood Samples	Fasting Blood Samples
	Weight	Weight	Weight	Weight
	Waist & Hip Circumference	Waist & Hip Circumference	Waist & Hip Circumference	Waist & Hip Circumference
	Resting HR ^c & BP ^d	Resting HR ^c & BP ^d	Resting HR ^c & BP ^d	Resting HR ^c & BP ^d
	REE ^e	REE ^e	REE ^e	REE ^e
	DEXA ^f	DEXA ^f	DEXA ^f	DEXA ^f
	GXT ^g			GXT ^g
	Isotonic Bench Press			Isotonic Bench Press
	Isotonic Leg Press			Isotonic Leg Press
				Post-study Questionnaire
^a Quality of Life, ^b Body Image Questionnaire, ^c heart rate, ^d blood pressure, ^e resting energy expenditure, ^f dual energy x-ray absorptiometry, ^g graded exercise test				

to abstain from exercise 48 hours prior to testing (once participating in the study), as well as from alcohol and over the counter medications 24 hours prior to testing. Participants were also required to have fasted for 12 hours prior to each testing session. Subjects were required to wear close-toed shoes and to not wear any metal. Participants reported to the Exercise and Sport Nutrition Laboratory (ESNL) the morning of each testing session at an

assigned time between 5:00am and 10:00am. Lab personnel confirmed that they brought their required diet and exercise log and that they had adhered to the pre-testing guidelines.

Curves[®] Complete 90-Day Fitness Challenge Program

The participants who were randomized into the Curves Complete (CC) group followed the protocol outline in Table 2. The macronutrient breakdown of the CC group was a ratio 45:30:25 of protein, carbohydrates, and fat respectively. The first week of the program consisted of a 1,200 kilocalorie diet, and the remaining 11 weeks were allotted 1,500 kilocalories. ESNL personnel explained with each subject the Curves diet as well as the exercise protocol. Participants were given a “Curves Fitness and Weight Management Plan” book [186] and “The Curves Food & Exercise Diary” [187] to help assist in following the diet plan. They were also provided with “Curves Essentials 2 Go” supplements, which consisted of two calcium tablets, one multi-vitamin tablet, and an omega-3 gel-capsule. They were required to exercise on the Curves circuit, which was located in the ESNL, four times per week. Each participant had an assigned key which was set-up to help track the number of workouts per week and the intensity of each workout. There were 13 hydraulic machines that were part of the Curves circuit. Three of the workouts consisted of a 30-second alternation between a Curves machine and calisthenics exercises, to maintain heart rate (HR). During these 30-minute sessions, participants completed two rounds of the circuit. The fourth workout involved alternating every minute between a Curves machine and Zumba dancing. There was a certified Zumba instructor who provided guidance and instruction on proper Zumba technique. For a Zumba workout, the circuit was only completed once.

On the remaining three days of the week, when the participants were not exercising on the Curves circuit, they were encouraged to walk for at least 30-minutes. In order to help encourage exercise on those days, participants in the Curves group were given a pedometer (Sportline 370 Multi-Function TraQ Any-Wear Pedometer, Yonkers, NY, USA) to wear each day while participating in the study. The pedometer was programmed for each subject individually, which included include height, weight, age, and step length. They were instructed to wear the pedometer on the waistband of their pants from the time they got out of bed in the morning until the time they returned to bed at the end of the day. The pedometer tracked the number of steps taken each day, and the participants were required to record their steps at the end of each day for the entire 12 weeks. The ultimate goal each day was to complete 10,000 steps.

Weight Watchers® Points Plus Program

The subjects who were randomized into the Weight Watchers (WW) group were enrolled in the Weight Watchers® PointsPlus Program and were required to attend a weekly meeting at a Weight Watchers facility. Each food item was given a point value, and each participant was allotted a specific total points for each day. The total points were based on entry level demographics, such as height, weight, age and gender, which was provided at registration of the program. The points system is formulated based on a food's protein, carbohydrate, fat, and fiber content [188]. Participants were required to purchase their own food and had the opportunity to buy specific Weight Watchers items from their local Weight Watchers facility. A goal of Weight Watchers is for the individual to be able to track the points throughout the day and obtain the required nutrients. At the weekly

Table 2: Curves diet protocol.

Diet Period	Total Kcal^a/Day	Group	Macronutrient	Grams/Day	Kcal/Day	Percentage Daily Diet (%)
Phase 1 (1 Week)	1,200 kcal/d	High Protein Diet + Exercise	PRO ^b CHO ^c FAT	135 90 33	540 360 300	45 30 25
Phase 2 (11 weeks)	1,500 kcal/d	High Protein Diet + Exercise	PRO ^b CHO ^c FAT	169 113 42	675 450 375	45 30 25
^a kilocalories, ^b protein, ^c carbohydrates						

meetings, the participants were able to ask questions regarding their diet and exercise and the meeting facilitator provided feedback to encourage positive changes to further promote weight-loss. The participants were encouraged to exercise and more specifically, to participate in organized walking sessions, but exercise was not required during the 12 weeks of participation in the study.

Jenny Craig[®] At Home

The subjects who were randomized into the Jenny Craig (JC) group were enrolled in the Jenny Craig[®] At Home program, which is an online-based program. Once registered by lab personnel, the participants received their meals every two weeks from Jenny Craig Inc. (Carlsbad, CA). The meals were assigned as breakfast, lunch, dinner, snacks, and desserts. Participants also supplemented their meals with their own fresh vegetables, fruits

and dairy products. A main focus of the JC program is portion control and a balanced approach to life, which includes meals [189]. Each participant was given a calorie level that was designed to help promote a one to two pound weight loss each week or one percent of the baseline weight. Menus were personalized to implement the most recent Dietary Guidelines for Americans and the Dietary Reference Intakes issued by the Institute of Medicine. The daily nutrients breakdown (given a 1,200 kilocalorie diet) were as the following: two grams of sodium, two grams of potassium, 100-200 milligrams of cholesterol, 20-30 grams of fiber, and 1,000 milligrams of calcium. The nutritional composition breakdown consisted of 50%-60% carbohydrates, 20%-30% protein, and 20%-30% fat. Participants were required to participate in a 10-15 minute weekly phone session, and each JC subject had a personal consultant who called them each week at an agreed upon time. The consultants were able to answer potential questions about the diet and give exercise suggestions to the individual. The JC program includes the one-on-one time to help improve self-monitoring, goal-setting, problem-solving and coping skills, with a three-part focus of Food, Body, and Mind. Though exercise was not required in the JC program, it was highly encouraged. The ultimate goal for exercise was to gradually work up to 30 minutes or more of moderate exercise on five or more days of the week. Subjects also had access to additional resources through Jenny Craig such as a Progress/Weight Tracker, Activity Planner, Online Journal, Message Boards, Chat Rooms, and a personal YourStyle® Profile.

Nutrisystem® Advance Select™ Program

The women who participated in the Nutrisystem (NS) group were enrolled in the Nutrisystem® Advance Select™ Program. The meal plan for each of the subjects was the fresh/frozen option, and the participants received a variety of foods every 28 days which included both nonperishable food items as well as those that needed to be stored in the freezer. The meals included breakfast, lunch, dinner, two snacks, and an additional snack or dessert for each day. The NS program focuses on the Glycemic Index (GI) and emphasizes carbohydrates that have a lower GI, due to the fact that they digest more slowly, which can help to maintain balanced blood sugar levels [170]. Also due to a slower transit time with low GI foods, there is able to be a greater sense of satiety which can improve the body's ability to burn calories more efficiently. Another component of NS meals is that they are high in protein, which is also able to help increase a sense of satiety for both after and between meals. The program emphasizes increased protein, because it helps to maintain muscle mass, which further improves the burning of calories. Nuts were one source of protein utilized in NS meals, because they provide a healthy source of fats. The meals also contained 1,800 to 2,200 milligrams of sodium each day. Subjects were given the option to remove and replace food items according to their likes and dislikes of food. However, the meal plans still maintained all the requirements under the Nutrisystem® Advance Select™ Program guidelines. The participants were given the option of calling a NS consultant whenever needed in order to answer questions and/or for assistance with meal and exercise options. There were online resources available that included interactive tracking tools. Participants were able to track their food, fitness,

weight, water and other components. Contacting counselors, dietitians, and other NS members was also available through the online resources, to help increase success in the program. In the NS group, exercise was encouraged, and walking specifically was emphasized. The goal was to incorporate 10 minutes of physical activity, three times per day.

Procedures

Diet Analysis

Participants recorded three weekdays and one weekend day of their food and fluid (excluding water) intake prior to each of the four testing sessions. Dietary information was analyzed to determine the average caloric intake and macronutrient intake using Food Processor Nutrition Analysis Software Version 10.12.0 (ESHA Nutrition Research, Salem, OR). A registered dietitian reviewed all of the analyzed dietary information.

Participants also completed an Eating Satisfaction Survey (Appendix E). The survey questions were categorized into: appetite, hunger, satisfied food, fullness, energy, and quality.

Physical Activity Analysis

Participants completed a seven day record of their physical activity (Appendix H) prior to each of the four testing sessions. The type of activity, the intensity, and the duration were included in the recording. The International Physical Activity Questionnaire (IPAQ) was also utilized at each of the four testing sessions to assess physical activity as well. The questionnaire evaluated the quantity of walking, moderate, vigorous, and total

(walking + moderate + vigorous) physical activity as MET-min/wk in the four areas of: work, transportation, household activities, and sitting.

Anthropometric Measurements

Height and weight measurements were obtained at the familiarization session, and participants were also weighed at weeks 0, 4, 8, and 12. Measurements were taken by using a Healthometer (Bridgeview, IL, USA) self-calibrating digital scale, which had a precision of ± 0.02 kg. Waist and hip measurements in centimeters were also measured by using a Gulick II tape measure. The protocol for the measurements followed the guidelines given by the American College of Sports Medicine (ACSM) [142].

Heart Rate and Blood Pressure

Resting heart rate (RHR) was determined by palpating the radial artery and also adhered to standard ACSM [142] procedures. Resting blood pressure was measured in the supine position after the participant had rested for five minutes. A mercurial sphygmomanometer (American Diagnostic Corporation, model #AD-720, Hauppauge, NY, USA) was utilized and measurements followed standard procedures.

Resting Energy Expenditure

Resting energy expenditure (REE) was measured using the ParvoMedics TrueMax 2400 Metabolic Measurement System (ParvoMedics Inc., Sandy, UT). Participants were fasted for 12 hours and laid in a supine position on the exam table. Their legs were elevated and rested on a padded box, in order to enhance comfort. A clear plastic hood and canopy were placed over their head and neck. Tubing connected the hood to the metabolic measuring system. Subjects were instructed to remain as still as possible for 20 minutes

without falling asleep. Oxygen and carbon dioxide exchange were measured. Metabolic measurements were recorded after 10 minutes and averaged from a five minute time segment where the principle variables (e.g. VO_2 L/min) changed less than five percent [191]. The manufacturer reported that the coefficient of variation for the device is $\pm 2\%$ in lean, healthy individuals.

Dual Energy X-Ray Absorptiometry

Body composition was determined by using the Hologic Discovery W QDR series Dual Energy X-ray Absorptiometry (DEXA) system (Watham, MA). The DEXA consisted of a low dose x-ray scan of the entire body (excluding the head) in order to determine fat mass, fat-free mass, and body fat percentage. Quality control (QC) calibration procedures were performed at the start of each testing session day. The QC scan was completed on a spine phantom (Discovery W-CALIBER Model DPA/QDR-1 anthropometric spine phantom). Participants were informed prior to the scan of any potential risks that could occur from being exposed to the small amount of radiation and were required to give consent by signing a Radiation Exposure Questionnaire (Appendix H) prior to each scan. Subjects were instructed to remove any metal from the body prior to laying supine on the scanning table. The arm scanned the participant for approximately six minutes. Participants were instructed to close their eyes when the arm scanned over their head, and their feet were secured by using sticky tape. Radiation exposure from the DEXA scan was approximately 1.5 mR per scan. This amount of radiation is comparative to the amount of natural radiation a person would be exposed to in one month of living in College Station, Texas. Throughout the study, the approximate dose that was received for

each subject was less than 9 mR. Previous research has shown that using DEXA as a means of determining body composition is a valid form of measurement [192, 193]. Additionally, there have been test-retest reliability studies conducted on fat free/soft tissue mass on the DEXA that have found mean coefficients of variation of 0.31-0.45% with a mean intra-class correlation of 0.985 [194].

Peak Aerobic Capacity

Participants performed a graded exercise test (GXT), which included a 12-lead echocardiogram (ECG), in order to determine peak aerobic capacity ($\text{VO}_{2\text{max}}$). Cardiopulmonary exercise tests were conducted at baseline and at 12 weeks. Each test was staffed by ESNL exercise physiology graduate students in accordance with standard procedures given by the American College of Sports Medicine's (ACSM) *Guidelines for Exercise Testing and Prescription* [142]. The Nasiff Cardio Card electrocardiograph (Nasiff Associates, Inc, Central Square, NY, USA) was used to assess heart function during each test. Subjects started-out in a supine position on the preparation table, and resting blood pressure was determined in order to be certain it was within the required range. The participants were prepped for the ECG. Electrode sites were cleansed with a sterile alcohol wipe, and the electrodes were placed at 10 sites including: right subclavicular fossa (RA), left subclavicular fossa (LA), fourth intercostal space at the right sternal border (V1), fourth intercostal space at the left sternal border (V2), half way between V2 and V4 (V3), fifth intercostal space at the mid-clavicular line (V4), fifth intercostal space at the anterior axillary line (V5), fifth intercostal space at the midaxillary line (V6), right abdominal line (RL) and left abdominal (LL) line. The ECG was printed

while the participant was in the supine position and was reviewed by lab personnel. Lab personnel made certain there were no contraindications which would prevent the participants from being involved in the exercise testing. Subjects were asked to step onto the treadmill and stood with their hands by their side. An additional ECG reading, blood pressure, and heart rate measurement were obtained. A sterile mouth piece was placed in the participant's mouth, and the head gear was adjusted and placed over the head. A nose clip was placed on the nose to make sure all gas flow occurred via the mouth. Tubing was connected from the mouth piece to the metabolic measuring system. Gas exchange measurements were obtained by using a ParvoMedics 2400 TrueMax Metabolic Measurement System (ParvoMedics Inc., Sandy, UT, USA). The participants followed the Bruce Protocol [195, 196] for the treadmill testing procedures. When the participant was ready to start the warm-up portion of the testing, the treadmill was adjusted to a speed of 2.0 mph and 0% grade. Subjects were asked to walk with their hands by their side throughout the testing but were allowed to place the back of their hands against the handrails if needed for stability purposes. After the two-minute warm-up stage, the speed decreased to 1.7 mph, and the grade increased to 10%. The participants were encouraged to continue on the treadmill to the highest stage they were able to reach. The ECG was monitored throughout the testing and lab personnel checked for any signs to end testing, according to ACSM guidelines [142]. Throughout testing, heart rate (HR), ECG, and gas exchange were monitored. Blood pressure (BP) and ratings of perceived exertion (RPE) were also obtained in the last 45 seconds of each stage. Once the participants were unable to continue testing, they grabbed the handrails, and lab personnel initiated the cool-down

period. Peak BP, RPE, ECG, and HR were measured, and the head gear, mouth piece, and nose clip were removed. There were three minutes of an active recovery period while the participant continued walking on the treadmill, and there was also an additional three minutes of passive recovery, while the participant was seated in a chair. HR, BP, ECG, and RPE was continued to be monitored during that time.

Isotonic Strength and Endurance Tests

Leg press and bench press were performed at baseline and 12 weeks in order to determine one repetition maximum (1RM) and 80% of 1RM. Participants' leg strength and endurance were determined by using a standard hip sled/leg press (Nebula Fitness, Versailles, OH, USA), and their upper body strength and endurance were determined by using an isotonic bench press and the Nebula Fitness (Versailles, OH, USA) Olympic Power Station (#1005). When the tests were performed by resistance-trained subjects in previous studies conducted in the ESNL, test-retest reliability comparisons have revealed low mean coefficients of variation as well as high reliability (1.9% bench press, intraclass $r=0.94$ and 0.7% leg press, intraclass $r=0.91$) [197]. The location of the seat and foot placement on the leg press were determined for each participant and maintained for each testing session. The protocol for both leg press and bench press were the same. The testing started with a warm-up consisting of two sets of 10 lifts without any added weight. Weight was added to the bar and participants lifted it for one repetition. A two-minute rest period was given between each set, throughout the entire strength testing. After each rest period, weight was added (approximately five to 10 pounds for bench press and approximately 10-25 pounds for leg press) until the 1RM was obtained. Once 1RM was determined, there

was a four-minute rest period prior to the endurance part of the testing. Muscular endurance was assessed by having the participants lift the bar with 80% of their 1RM as many times as they could while maintaining standard lifting techniques and testing criteria [198].

Blood Collection

Fasting blood profiles were obtained in order to measure cholesterol, triglycerides, HDL-cholesterol, LDL-cholesterol, glucose, liver enzymes, whole blood analysis, insulin, and leptin. Participants were fasted for 12 hours and had not exercised 48 hours prior to each blood draw. Whole blood and serum samples were collected following standard phlebotomy procedures by giving a sterile venipuncture of an antecubital vein. After collection, the tubes of blood were centrifuged at 1100 x g for 15-minutes in a standard bench top centrifuge (Cole Palmer, Vernon Hills, IL, Model #17250-10). An Abbott Cell Dyn 3500 automated hematology analyzer (Abbott Laboratories, Abbott Park, IL, USA) was used to analyze the whole blood samples. The samples were analyzed in order to obtain complete blood cell counts. Some serum was pipetted from the collection tube and placed into micro-centrifuge tubes. They were then frozen at -80° C to be analyzed at a later time. A complete metabolic panel was also obtained after analyzing the remaining serum samples by Quest Diagnostics (Quest Diagnostics, 5850 Rogerdale Road, Houston, TX, USA 77072). An Olympus AAU 5400 Chemistry Immuno Analyzer (Olympus America Inc., Center Valley, PA, USA) was utilized for the analyses.

Fasting insulin levels were assayed in duplicate by using a commercially available enzyme linked immunoabsorbent assay (ELISA) kit and a BioTek ELX-808

Ultramicroplate reader (BioTek Instruments Inc., Winooski, VT). It was set at an optical density of 450 nm against a known standard curve and used standard procedures from BioTek Gen5 Analysis software (BioTek Instruments Inc., Winooski, VT). The intra-assay coefficient of variation has been shown to range from 2.9% to 6.2%, and the inter-assay coefficient of variation has ranged from 5.4% to 8.6% (ALPCO, Salem, NH). Homeostasis Model Assessment for Insulin Resistance (HOMA-IR) was calculated by multiplying fasting insulin ($\mu\text{U/mL}$) and fasting glucose (mg/dL), then dividing by 405 [199].

Fasting serum leptin levels were determined in duplicate by using a BioTek ELX-808 Ultramicroplate reader (BioTek Instruments Inc., Winooski, VT). An optical density of 450 nm was also used and common analyzing procedures were followed using BioTek Gen5 Analysis software (BioTek Instruments Inc., Winooski, VT). Intra-assay coefficient of variation has been shown to range from 3.7% to 5.5%, and the inter-assay coefficient of variation of has ranged from 5.8% to 6.8% (ALPCO, Salem, NH).

Psychosocial Evaluations

Questionnaires were completed by the participants, including a standardized Quality of Life Questionnaire (SF-36) [200, 201], and a Body Image Questionnaire. The SF-36 Quality of Life Questionnaire has been used as a psychosocial evaluation and results may be impacted by general improvements in health and/or weight loss [202, 203]. The questions helped to assess various physical and mental components, including physical functioning (the ability to perform vigorous physical activities without being limited by health), role physical (the ability to work and perform daily activities), bodily

pain (limitations during the day due to pain), general health (evaluation of personal health), vitality (perception of energy level), social functioning (the ability to perform normal social activities), role emotion (difficulties with work or other daily activities), and mental health (the state of feeling peaceful, happy, and calm).

The Body Image Questionnaire is comprised of three different sections. The first is the Rosenberg Self-Esteem Scale (RSE) [204]. The RSE measures self-esteem by using a four-point Likert scale. It ranges from one (strongly agree) to four (strongly disagree). Total scores range from 10 to 40; the higher the score, the greater the correlation with higher self-esteem. The second section is Social Physique Anxiety Scale (SPAS) which was developed by Hart and colleagues in 1989 [205]. It consists of 12 questions that use a five-point Likert scale. It ranges from one (not at all true) to five (extremely true). Totals range from 12 to 60, with an increase in social physique anxiety correlating with an increase in score. This portion of the questionnaire is used to evaluate the level of anxiety an individual experiences as a result of the degree to which it is perceived that others are devaluing her body. Several studies have shown the internal consistency ($r=0.90$), predictive validity, and the construct validity [205-207]. The third section of the questionnaire is the Multidimensional Body-Self Relations section (MBSRQ-AS). It consists of five sections: Appearance Evaluation, Appearance Orientation, Overweight Preoccupation, Self-Classified Weight, and the Body Areas Satisfaction Scale (BASS). It's on a five point scale from one (strongly disagree) to five (strongly agree). At the completion of the study, participants were asked to fill-out a post-study questionnaire in

order to provide feedback pertaining to their experience as a participant in the weight-loss study.

Cost to Benefit Analysis

In an attempt to assess costs of the diets used, a random sample of 10 participants' food logs for one week were analyzed to determine the cost of the program and food. Food costs were estimated according to the price of purchased foods that were described on a given food log. The costs were then averaged and applied to each subject for the duration of the study. The cost per day (CC 6.4 ± 1.6 , WW 4.9 ± 1.4 , JC 2.2 ± 1.1 , NS 1.8 ± 1.1 , C 4.7 ± 2.2 \$/day) was used to calculate an average 90 day food cost (CC 579 ± 147 , WW 438 ± 130 , JC 200 ± 101 , NS 162 ± 103 , C 422 ± 198 \$/90 days). The 90 day food cost was then added to the program participation costs (CC 300, WW 120, JC 2,400, NS 900, C 0 \$/90 days) in order to estimate a total cost (CC 879 ± 147 , WW 558 ± 130 , JC $2,600 \pm 101$, NS $1,062 \pm 103$, C 422 ± 198 \$/90 days) per program [208].

Statistical Analysis

Analysis was conducted on all participants who completed the 12 weeks of the study. One-way Analysis of Variance (ANOVA) was used to analyze baseline demographic data, and data were normally distributed. Multivariate Analysis of Variance (MANOVA) with repeated measures was used to analyze related variables with the IBM SPSS for Windows Version 20 software (IBM Corporation, Armonk, NY). If there were instances where data was missing, they were replaced by using the last observed value. However, with the nutrient data, missing data was replaced with the series mean. Overall MANOVA effects were assessed by using Wilks' Lambda time and diet x time p-levels.

Each variable that was analyzed by MANOVA, Greenhouse-Geisser univariate tests of within-subjects time and diet x time effects and between-subjects univariate diet effects were reported. Non-related variables were analyzed by repeated measures ANOVA with univariate time, time x diet, and diet effects reported. Tukey's least significant difference (LSD) post hoc analyses was also utilized in order to determine at which time point and between which diets the significance was obtained. Weight, body mass index, International Physical Activity Questionnaire, scanned mass, scanned fat mass, scanned fat-free mass, scanned percent body fat, resting energy expenditure, nutrient intake, Eating Satisfaction Survey, anthropometrics, heart rate, blood pressure, peak aerobic capacity, and psychosocial variables are reported as delta changes from baseline. Lipids, hormones, and muscular strength changes are presented as percent change from baseline. The first testing session (T1) was subtracted from the final testing session (T4) in order to determine the delta values: (T4-T1). In order to determine percent change, T1 was subtracted from T4, then divided by 100. The total was then multiplied by 100: $100[(T4-T1)/T1]$. The delta changes and percent changes were calculated and then also analyzed by ANOVA or MANOVA with repeated measures in order to evaluate the changes from baseline. Data were considered statistically significant when the probability of type I error was less than or equal to 0.05. Data were considered to have statistical trends when the p-value was set between 0.05 and 0.10. Data was presented as means \pm standard deviation, except group means were presented as means \pm standard error mean. The sample had sufficient power (CC n=29; WW n=29; JC n=27; NS n=28; C n=20) in order to assess statistically

significant changes. A sample size of 20 per group was needed for there to be a power of 0.8 at a 0.05 α -level.

CHAPTER IV

STUDY OUTCOME*

Results

Baseline Demographics

No significant differences were seen at baseline between the five groups in age, height, weight, body mass index (BMI), or body fat percentage, which was found when analyzed by ANOVA. As denoted in Table 3, there were 133 women who completed the 12 week intervention. Baseline demographics consisted of age 47.2 ± 11.3 yrs, height 161.9 ± 6.7 cm, weight 86.3 ± 14.1 kg, BMI 35.5 ± 5.6 kg/m², and body fat percentage $45.8 \pm 4.5\%$.

Table 3: Baseline demographics for all groups. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C).

Variable	Mean	CC	WW	JC	NS	C	P-value
Age (yrs)	47.2±11.3	46.5±10.1	48.2±10.8	46.0±12.4	45.6±12.4	50.6±10.9	0.57
Height (cm)	161.9±6.7	161.4±6.5	164.4±6.8	160.7±7.0	161.7±5.6	161.1±7.6	0.25
Weight (kg)	92.8±14.6	90.7±13.6	91.1±14.4	91.0±14.6	96.8±15.9	95.0±14.2	0.41
BMI ^a (kg/m ²)	35.5±5.6	34.9±5.9	34.2±6.4	35.1±4.5	36.9±5.2	36.5±5.2	0.34
Body Fat (%)	45.8±4.5	45.6±3.7	44.2±4.8	46.6±3.9	46.5±4.6	46.3±5.2	0.22
Significance level was set at $p < 0.05$. Mean (n=133), CC (n=29), WW (n=29), JC (n=27), NS (n=28), C (n=20). ^a = Body Mass Index							

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Participant Consort

There were 356 women who passed the initial phone screening and who then attended a familiarization (FAM) session. Of those who signed a consent form and who were eligible to participate, 210 were randomized into one of the five groups. Of the

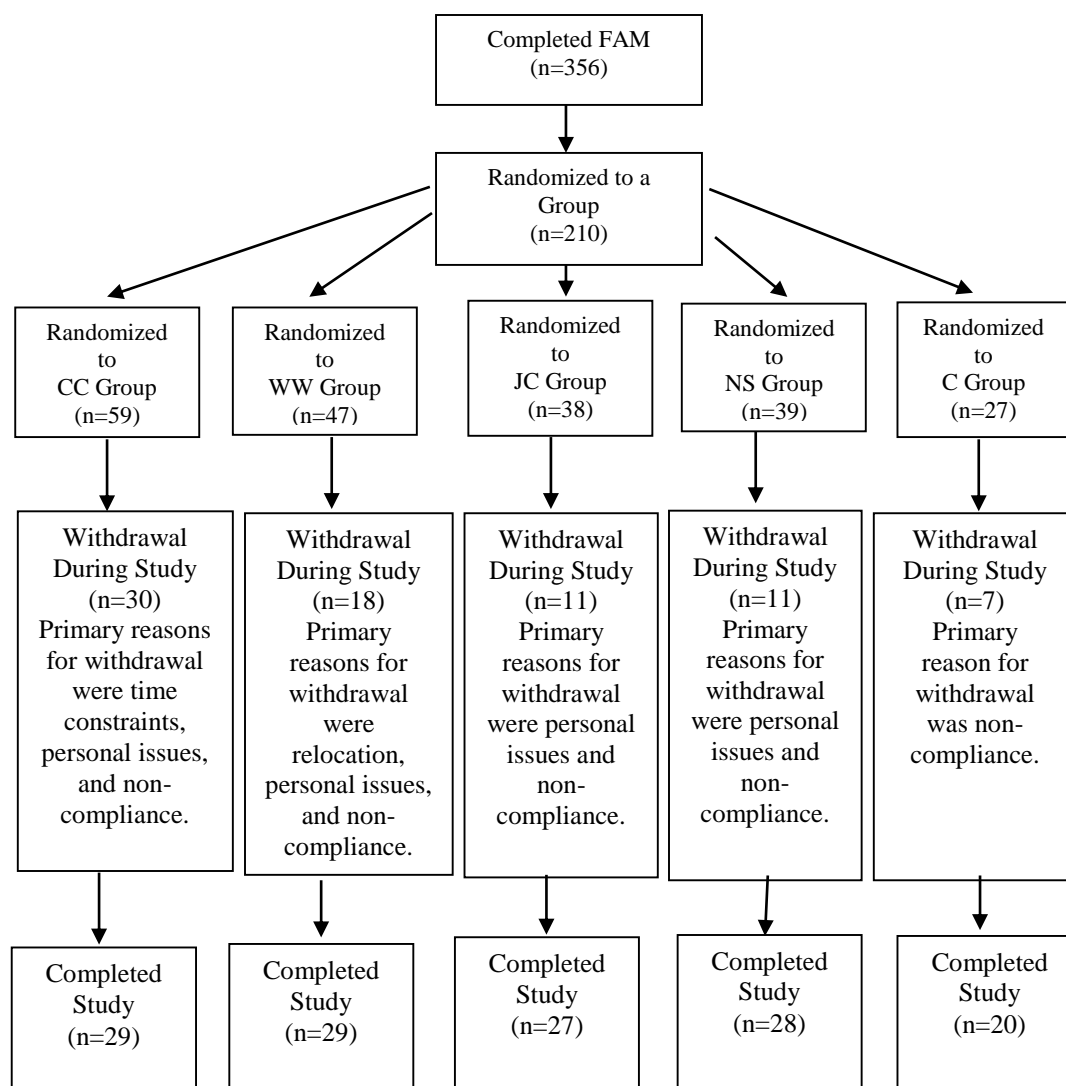


Figure 1: Participant consort.

210 who were randomized, 146 individuals withdrew prior to baseline testing, and 77 participants withdrew after having completed one or more testing sessions, as depicted in Figure 1.

Energy Intake

Energy intake was measured at 0, 4, 8, and 12 weeks by a self-reported four day diet log. Participants recorded three week day and one weekend day of their dietary intake prior to each testing session. A one-way MANOVA was run to analyze total energy intake expressed as kilocalories (kcal) per day and kcal per grams per day. An additional MANOVA was run to determine macronutrient breakdown and was expressed as grams per day, grams per kilogram per day, and percentage of macronutrients of total calories consumed.

Absolute Energy Intake

There was an overall time (Wilks' Lambda $p<0.001$) and time x diet (Wilks' Lambda $p<0.001$) effect for absolute energy intake. MANOVA univariate revealed a time ($p<0.001$) and diet ($p<0.001$) effect for total energy intake when expressed as kcal per day and grams per day. Table 4 shows how all groups experienced a decrease in energy intake over the 12 weeks. As seen in Figure 2, when analyzed as delta changes from baseline, NS had the greatest decrease in absolute energy intake (CC -303 ± 507 , $p=0.043$; WW -527 ± 849 , $p<0.001$; JC -556 ± 758 , $p<0.001$; NS -630 ± 424 , $p<0.001$; C -316 ± 767 kcal/day, $p=0.05$). When assessing protein intake as delta changes from baseline, CC was the only group that had a trend toward an absolute protein increase at week 8 ($p=0.093$). Protein intake significantly decreased by week 12 in the JC group (-14.1 ± 24.2 g/day $p=0.031$).

The NS and C groups experienced a significant decrease in protein intake at week 4 ($p=0.022$) and weeks 4 ($p=0.014$) and 8 ($p=0.011$) respectively. However, neither were significantly less by the end of the 12 weeks. WW had a trend toward a significant decrease at week 8 ($p=0.055$). CC was the only group to have an increase in protein (9.4 ± 27.2 g/day) at week 12 compared to WW (-9.1 ± 42.5 , $p=0.045$), JC (-14.1 ± 24.2 , $p=0.013$), and C (-10.7 ± 35.0 , $p=0.046$), and a trend was seen when compared to NS (-8.0 ± 35.0 g/day, $p=0.063$). When assessing carbohydrate intake, there was a significant decrease in absolute carbohydrate in the CC group at week 4 (-56.6 ± 88.7 , $p=0.006$), week 8 (-58.9 ± 78.3 , $p=0.002$), and week 12 (-62.6 ± 82.4 g/day, $p=0.002$). WW also experienced a decrease in carbohydrate intake at weeks 4 (-49.4 ± 111.2 , $p=0.008$), 8 (-48.6 ± 108.4 , $p=0.005$), and 12 (-46.2 ± 115.5 g/day, $p=0.011$). There was a decrease in carbohydrates for NS at weeks 4 (-87.9 ± 87.2 , $p<0.001$), 8 (-88.4 ± 87.4 , $p<0.001$), and 12 (-89.3 ± 76.1 g/day, $p<0.001$) as well. The C group had a trend toward a decrease at weeks 4 ($p=0.070$) and 8 ($p=0.089$) but not at week 12. Also at week 12, CC was trending toward a significantly greater decrease in carbohydrates than JC ($p=0.094$). NS had a significantly greater decrease in carbohydrate compared to JC at week 12 (-89.3 ± 76.1 vs -16.0 ± 83.2 , $p=0.007$), and there was a trend when compared to the C group (-33.1 ± 103.0 g/day, $p=0.051$). CC, WW, JC, and NS all had a significant decrease in fat intake compared to baseline at all three time points with NS having the greatest decrease. When expressed as delta changes at week 12, CC (-15.8 ± 34.0 , $p=0.018$), WW (-24.4 ± 32.2 , $p<0.001$), JC (-32.7 ± 28.9 , $p<0.001$), and NS (-39.0 ± 27.1 g/day, $p<0.001$). NS had a significantly greater reduction in absolute fat intake compared to CC (NS -41.4 ± 27.7 , CC -20.7 ± 33.9 g/day,

Table 4: Changes in absolute dietary intake. Observed between groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C).

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Energy Intake (kcal/day)	CC	1,747.5 ^j ± 515	1,351 [‡] ± 228	1,397 [‡] ± 311	1,445 [‡] ± 430	1,485 ± 72.8	T = 0.001
	WW	1,871 ± 859	1,331 [‡] ± 352	1,326 [‡] ± 340	1,344 [‡] ± 386	1,468 ± 65.7	D = 0.001
	JC	1,826 ± 721	1,353 [‡] ± 318	1,438 [‡] ± 756	1,270 [‡] ± 279	1,472 ± 69.7	T x D = 0.628
	NS	1,882 ± 465	1,188 [‡] ± 186	1,257 [‡] ± 305	1,252 [‡] ± 280	1,395 ± 68.3	
	C	2,122 ± 718	1,681 ^{‡abcd} ± 510	1,783 ^{‡abcd} ± 582	1,807 ^{‡abcd} ± 554	1,848 [‡] ± 78.3	
	Mean	1,882 ± 674	1,365 ± 371	1,422 ± 508	1,403 [*] ± 427		
Protein Intake (grams/day)	CC	74.5 ± 17.7	83.1 ^{bode} ± 26.4	84.8 ^{‡bcde} ± 18.5	83.9 ^{bcd} ± 22.3	81.6 ± 74.9	T = 0.007
	WW	81.4 ± 42.3	71.1 ± 22.0	70.8 [#] ± 21.8	72.3 ^c ± 21.6	73.9 ± 67.9	D = 0.011
	JC	72.7 ± 22.7	65.5 ± 13.9	64.3 ± 13.9	58.6 ^{‡e} ± 15.0	65.3 ± 58.9	T x D = 0.051
	NS	77.4 ± 22.6	62.2 [‡] ± 16.0	68.4 ± 16.0	69.4 ± 20.1	69.4 ± 63.1	
	C	85.9 ± 29.5	67.1 [‡] ± 20.9	69.1 [‡] ± 27.2	75.1 ± 21.6	74.3 [‡] ± 67.2	
	Mean	78.2 ± 28.7	69.7 ± 21.1	71.3 ± 20.5	71.5 [*] ± 21.5		
CHO Intake (grams/day)	CC	186.5 ± 80.0	129.9 ^{‡ce} ± 33.4	127.7 ^{‡ce} ± 38.6	123.9 ^{‡ce} ± 50.9	142.0 ± 125.0	T = 0.001
	WW	190.8 ± 120.1	141.3 ^{‡ode} ± 41.5	142.2 ^{‡ode} ± 44.1	144.5 ^{‡ode} ± 51.2	154.7 ± 139.4	D = 0.001
	JC	188.0 ± 60.5	177.2 ^d ± 52.1	175.0 ^d ± 44.3	172.0 ^d ± 51.8	178.1 ± 161.8	T x D = 0.100
	NS	197.4 ± 79.1	109.5 ^{‡e} ± 47.1	109.1 ^{‡e} ± 47.6	108.1 ^{‡e} ± 40.1	131.0 ± 115.1	
	C	223.8 ± 91.6	184.1 [#] ± 48.7	189.3 [#] ± 60.7	190.7 ± 69.9	197.0 [‡] ± 178.7	
	Mean	196.2 ± 88.8	146.7 ± 52.3	146.8 ± 54.6	146.0 [*] ± 59.6		
Fat Intake (grams/day)	CC	74.3 ± 30.0	50.2 ^{‡cd} ± 18.9	53.6 ^{‡cd} ± 19.2	58.6 ^{‡cd} ± 23.8	59.2 ± 3.1	T = 0.001
	WW	72.4 ± 31.0	47 ^{‡cd} ± 18.9	46.7 ^{‡cd} ± 15.7	48.0 ^{‡c} ± 17.2	53.5 ± 2.8	D = 0.001
	JC	69.1 ± 25.8	35.3 [‡] ± 11.3	34.3 [‡] ± 15.7	36.4 [‡] ± 17.6	43.8 ± 3.0	T x D = 0.007
	NS	76.8 ± 26.4	31.5 [‡] ± 9.2	35.4 [‡] ± 14.0	37.8 [‡] ± 14.0	45.4 ± 2.9	
	C	81.4 ± 32.3	68.0 ^{‡abcd} ± 26.2	72.1 ^{‡abcd} ± 27.5	75.4 ^{‡bcd} ± 26.6	74.2 [‡] ± 3.4	
	Mean	74.5 ± 29.0	45.3 ± 21.1	47.2 ± 22.4	49.9 [*] ± 23.9		

Values are represented as means±standard deviation except group means are ±standard error mean. n = 117; CC (n=22), WW (n=27), JC (n=24), NS (n=25), and C (n=19). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p<0.05 (univariate). † = significant diet effect p<0.05 (univariate). ‡ = significant time effect from baseline p<0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. ^a = significantly different than CC (p < 0.05). ^b = significantly different than WW (p < 0.05). ^c = significantly different than JC (p < 0.05). ^d = significantly different than NS (p < 0.05). ^e = significantly different than C (p < 0.05). [#] = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). [†] = a trend toward significance compared to CC (p > 0.05 and p < 0.1). [‡] = a trend toward significance compared to WW (p > 0.05 and p < 0.1). ^h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). ⁱ = a trend toward significance compared to NS (p > 0.05 and p < 0.1). ^j = a trend toward significance compared to C (p > 0.05 and p < 0.1).

p=0.011). WW, JC, and NS all experienced significantly greater reductions in fat intake at week 12 compared to the C as well (WW -25.7±29.1, p=0.049, JC -34.8±28.7, p=0.006, NS -41.4±27.7, p=0.001).

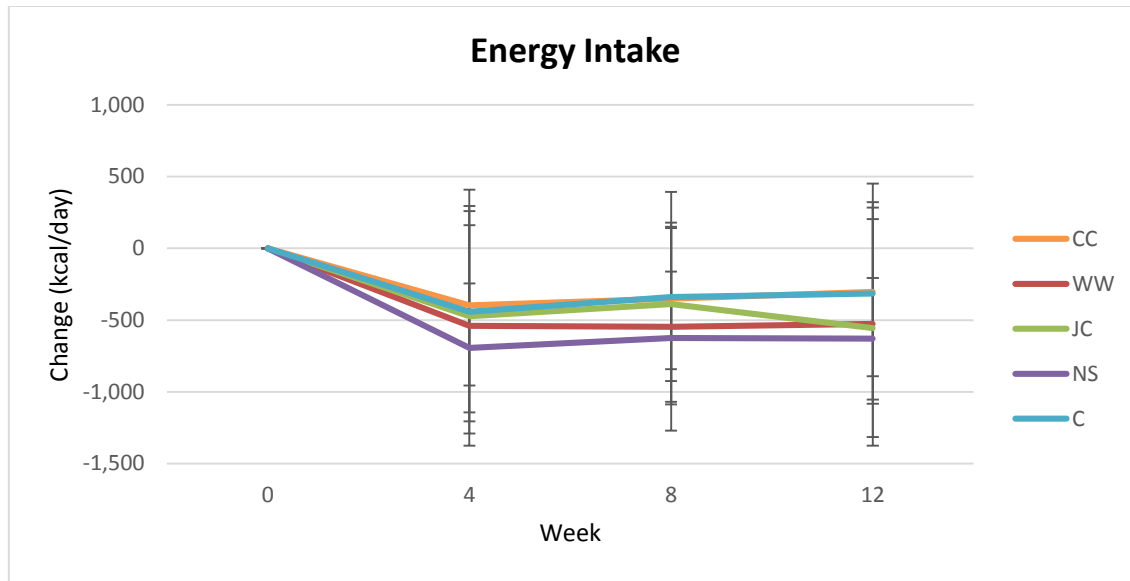


Figure 2: Changes from baseline in absolute energy intake over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. n=117.

Relative Energy Intake

There was an overall time (Wilks' Lambda $p<0.001$) and time x diet (Wilks' Lambda $p<0.001$) effect when expressed as kilocalories per kilogram per day and grams per kilogram per day. Similar findings were seen in total energy intake throughout the 12 weeks when based on kilograms of body weight and is depicted in Table 5. CC, WW, JC, NS, and C all experienced a significant time effect at weeks 4 (CC $p=0.013$, WW $p=0.001$, JC $p=0.002$, NS $p<0.001$, C $p=0.007$) and 8 (CC $p=0.023$, WW $p<0.001$, JC $p=0.007$, NS $p<0.001$, C $p=0.009$), and all but the CC group had a significant change from baseline at week 12 (CC -2.5 ± 6.7 , $p=0.122$; WW -4.6 ± 8.7 , $p=0.002$, JC -5.4 ± 8.6 , $p=0.001$; NS -5.6 ± 4.4 , $p<0.001$, -3.7 ± 9.1 , $p=0.038$), as well. When looking at protein intake represented as grams/kg/day, there was a significant time effect for the CC group at weeks 8 ($p=0.026$)

and 12 (0.2±0.3 g/kg/day, p=0.039), and for the C group at weeks 4 (p=0.011) and 8 (p=0.008) and a trend at week 12 (p=0.085). CC was the only group that had an increase protein intake at week 12 and was significantly different than WW (p=0.050), JC (p=0.017), and C (p=0.008) and a trend toward being significantly greater than NS (p=0.071), seen in Figure 3. When looking at carbohydrates relative to body weight, there

Table 5: Changes in relative dietary intake. Observed between diet groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C)

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Energy Intake (kcal/kg/day)	CC	19.8 ± 6.8	15.6 ^{‡i} ± 3.2	16.6 [‡] ± 5.1	17.2 ^d ± 5.6	17.3 ± 0.9	T = 0.001
	WW	20.6 ± 8.0	15.5 ^{‡i} ± 4.6	15.6 ^{‡i} ± 4.4	16.0 [‡] ± 5.0	16.9 ± 0.8	D = 0.023
	JC	20.8 ± 8.7	15.8 [‡] ± 3.6	17.1 ^{‡i} ± 9.3	15.4 [‡] ± 3.8	17.3 ± 0.9	T x D = 0.877
	NS	19.8 ± 4.2	13.1 ^{‡abce} ± 3.5	14.2 ^{‡e} ± 3.8	14.2 [‡] ± 3.4	15.3 ± 0.8	
	C	22.9 ± 9.1	18.0 [‡] ± 6.3	18.9 [‡] ± 5.8	19.2 ^{‡bcd} ± 6.3	19.7 [‡] ± 1.0	
	Mean	20.7 ± 7.4	15.5 ± 4.5	16.3 ± 6.1	16.2* ± 5.0		
Protein Intake (grams/kg/d)	CC	0.84 ± 0.21	0.95 ^{cddeg} ± 0.27	0.99 ^{‡bode} ± 0.20	0.99 ^{‡odeg} ± 0.25	0.94 ± 0.04	T = 0.082
	WW	0.91 ± 0.43	0.83 ^d ± 0.28	0.84 ± 0.28	0.86 ^c ± 0.29	0.86 ± 0.04	D = 0.011
	JC	0.82 ± 0.25	0.76 ± 0.15	0.77 ± 0.21	0.72 ± 0.23	0.77 ± 0.04	T x D = 0.036
	NS	0.82 ± 0.23	0.69 [#] ± 0.22	0.77 ± 0.19	0.79 ± 0.23	0.77 ± 0.04	
	C	0.93 ± 0.40	0.72 [‡] ± 0.24	0.73 [‡] ± 0.27	0.79 [#] ± 0.22	0.80 [‡] ± 0.04	
	Mean	0.86 ± 0.31	0.79 ± 0.25	0.82 ± 0.25	0.83 ± 0.26		
Carbohydrate Intake (grams/kg/d)	CC	2.28 ± 1.11	1.64 ^{‡ode} ± 0.50	1.65 ^{‡oei} ± 0.67	1.60 ^{‡oe} ± 0.70	1.66 ± 0.11	T = 0.001
	WW	2.27 ± 1.29	1.77 ^{‡ode} ± 0.55	1.81 ^{‡ode} ± 0.62	1.86 ^{‡od} ± 0.71	1.78 ± 0.10	D = 0.001
	JC	2.33 ± 0.92	2.21 ^d ± 0.53	2.25 ^d ± 0.60	2.26 ^d ± 0.73	2.10 ± 0.10	T x D = 0.207
	NS	2.22 ± 0.85	1.30 ^{‡e} ± 0.58	1.31 ^{‡e} ± 0.56	1.31 ^{‡e} ± 0.50	1.43 ± 0.10	
	C	2.61 ± 1.29	2.14 [#] ± 0.74	2.17 [#] ± 0.73	2.18 [#] ± 0.87	2.11 [‡] ± 0.12	
	Mean	2.33 ± 1.09	1.79 ± 0.66	1.8 ± 0.71	1.82* ± 0.77		
Fat Intake (grams/kg/d)	CC	0.91 ± 0.39	0.62 ^{‡ode} ± 0.22	0.69 ^{‡odj} ± 0.29	0.75 ^{‡odg} ± 0.29	0.69 ± 0.04	T = 0.001
	WW	0.85 ± 0.27	0.59 ^{‡ode} ± 0.26	0.60 ^{‡ode} ± 0.22	0.61 ^{‡ode} ± 0.23	0.62 ± 0.03	D = 0.001
	JC	0.84 ± 0.31	0.45 ^{‡e} ± 0.16	0.45 ^{‡e} ± 0.22	0.48 ^{‡e} ± 0.24	0.51 ± 0.04	T x D = 0.026
	NS	0.86 ± 0.25	0.38 ^{‡e} ± 0.13	0.43 ^{‡e} ± 0.18	0.46 ^{‡e} ± 0.17	0.50 ± 0.03	
	C	0.95 ± 0.41	0.78 [‡] ± 0.33	0.82 ± 0.28	0.86 ± 0.30	0.79 [‡] ± 0.04	
	Mean	0.88 ± 0.32	0.55 ± 0.26	0.58 ± 0.27	0.62* ± 0.28		
Values are+B12:S35 represented as means±standard deviation except group means are ±standard error mean. n = 117; CC (n=22), WW (n=27), JC (n=24), NS (n=25), and C (n=19). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p<0.05 (univariate). † = significant diet effect p<0.05 (univariate). ‡ = significant time effect from baseline p<0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC (p < 0.05). b = significantly different than WW (p < 0.05). c = significantly different than JC (p < 0.05). d = significantly different than NS (p < 0.05). e = significantly different than C (p < 0.05). # = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). f = a trend toward significance compared to CC (p > 0.05 and p < 0.1). g = a trend toward significance compared to WW (p > 0.05 and p < 0.1). h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). i = a trend toward significance compared to NS (p > 0.05 and p < 0.1). j = a trend toward significance compared to C (p > 0.05 and p < 0.1).							

was a significant time effect for CC and NS, with a decrease in carbohydrate intake at weeks 4 (CC $p=0.008$; NS $p<0.001$), 8 (CC $p=0.005$; NS $p<0.001$), and 12 (CC -0.6 ± 0.9 , $p=0.005$; NS -0.8 ± 0.8 g/kg/day, $p<0.001$), shown in Figure 4. WW also experienced a significant decrease at weeks 4 ($p=0.022$) and 8 ($p=0.022$) and a trend at week 12 was noted ($p=0.059$). The C group had a trend toward a significant decrease in carbohydrate

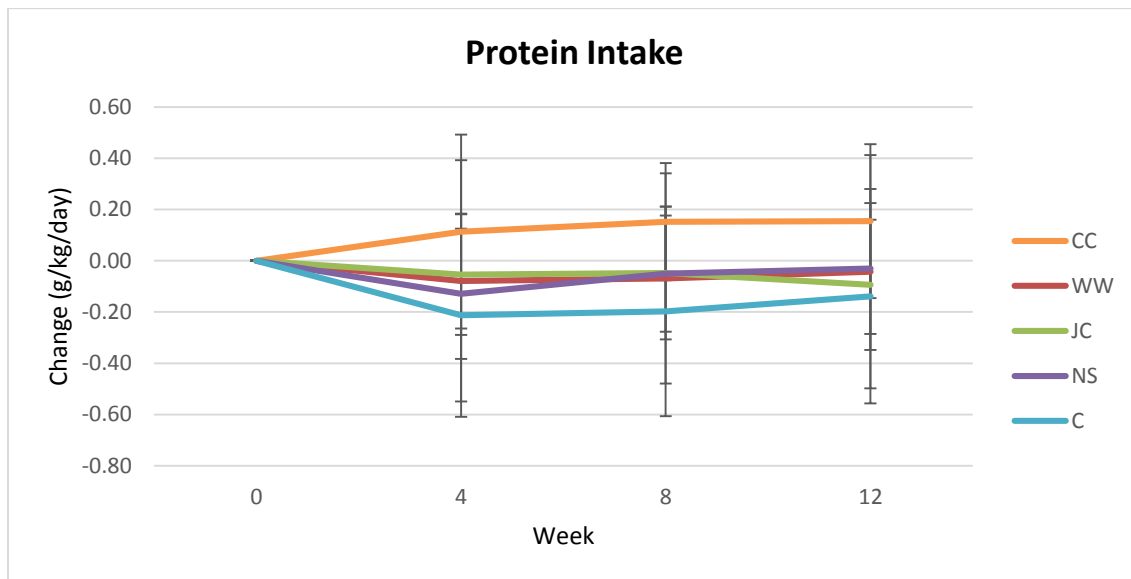


Figure 3: Changes from baseline in relative protein intake over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. $n=117$.

intake at weeks 4 ($p=0.069$), 8 ($p=0.069$), and 12 (-0.4 ± 1.2 , $p=0.092$). CC trended toward having a significantly greater decrease than JC ($p=0.072$) in carbohydrate intake at week 12. All diet groups had a significant decrease ($p<0.001$) in fat intake, and the average decrease for all the groups was -0.2 ± 0.3 g/kg/day, depicted in Figure 5.

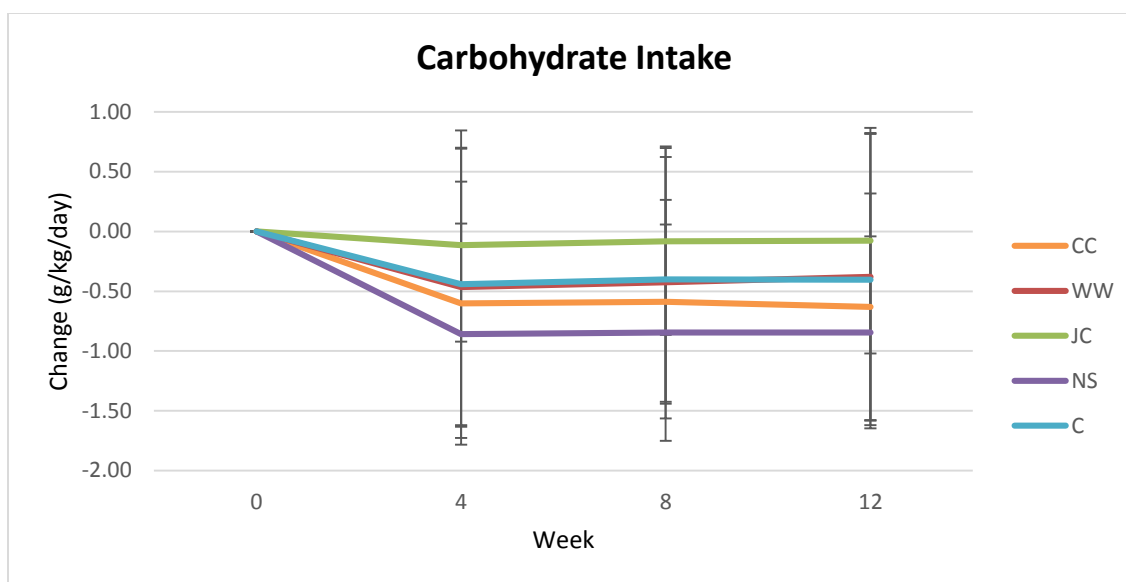


Figure 4: Changes from baseline in relative carbohydrate intake over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. n=117.

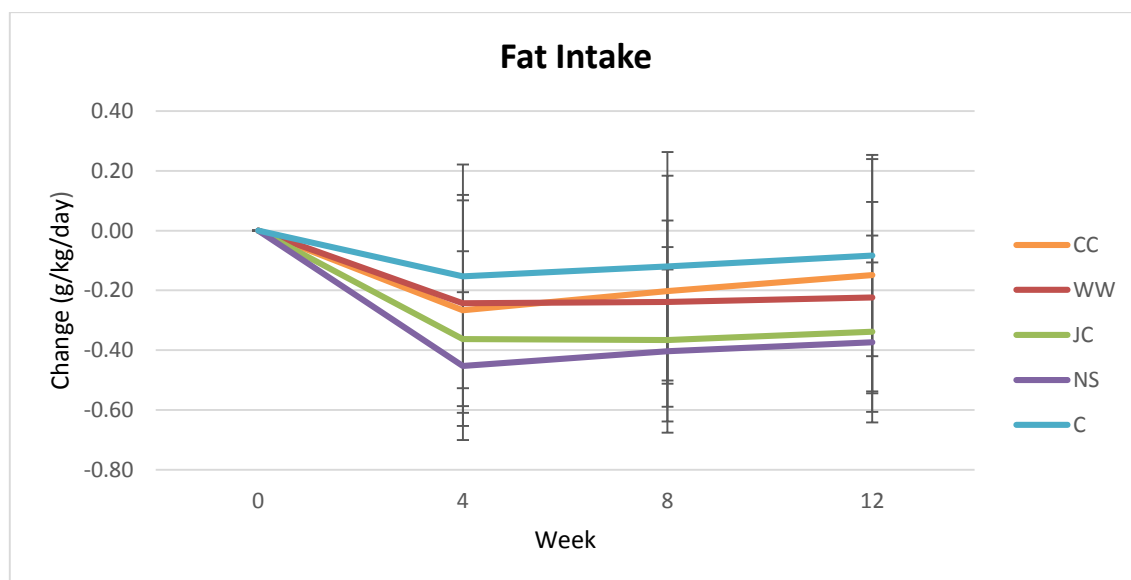


Figure 5: Changes from baseline in relative fat intake over 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. n=117.

Percent Energy Intake

Diets were also assessed as percentage of macronutrients in kilocalories to total kilocalorie intake. There was also an overall significant time (Wilks' Lambda $p < 0.001$) effect and time x diet (Wilks' Lambda $p < 0.001$) effect. Table 6 shows that CC, WW, and NS all had a significant increase in percent protein at weeks 4 (CC $p < 0.001$, WW $p = 0.013$, and NS $p < 0.001$), 8 (CC $p < 0.001$, WW $p = 0.006$, NS $p < 0.001$), and 12 (CC $p < 0.001$, WW

Table 6: Changes in percent dietary intake. Observed between diet groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C)

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Protein Intake (%total kcal)	CC	18.6 ± 5.1	25.6 ^{†bce} ± 7.0	26.1 ^{†bce} ± 6.2	25.7 ^{†ceg} ± 6.6	24.0 ± 0.8	T = 0.001
	WW	19.3 ± 4.5	22.5 ^{†de} ± 4.8	22.7 ^{†de} ± 6.4	22.7 ^{†cde} ± 5.1	21.8 ± 0.7	D = 0.001
	JC	17.9 ± 3.9	20.5 ^{†de} ± 3.6	20.4 ^{†de} ± 2.8	19.3 ^d ± 4.8	19.5 ± 0.7	T x D = 0.001
	NS	18.0 ± 5.2	26.2 ^{†e} ± 5.0	27.6 ^{†e} ± 6.5	26.9 ^{†e} ± 5.3	24.7 ± 0.7	
	C	18.0 ± 4.0	16.8 ± 3.6	16.6 ± 3.5	17.8 ± 3.7	17.3 [†] ± 0.8	
	Mean	18.4 ± 4.6	22.5 ± 5.9	22.9 ± 6.6	22.7* ± 6.2		
CHO Intake (%total kcal)	CC	42.8 ± 9.3	40.2 ^{bcei} ± 9.0	38.2 ^{†bce} ± 7.1	36.1 ^{†bcei} ± 8.1	39.3 ± 1.1	T = 0.095
	WW	42.3 ± 9.2	44.7 ^c ± 8.0	44.6 ^c ± 7.4	44.5 ^{ci} ± 8.6	44.0 ± 1.0	D = 0.001
	JC	45.6 ± 8.4	54.7 ^{†de} ± 6.0	55.3 ^{†de} ± 9.9	54.8 ^{†de} ± 9.4	52.6 ± 1.1	T x D = 0.001
	NS	43.5 ± 10.6	43.9 ± 7.2	41.2 ± 9.7	40.4 ± 8.3	42.3 ± 1.1	
	C	45.2 ± 5.6	46.1 ± 4.5	45.3 ± 5.3	43.5 ± 7.1	45.0 [†] ± 1.2	
	Mean	43.8 ± 8.8	46.0 ± 8.6	45.0 ± 9.9	44.0 ± 10.3		
Fat Intake (%total kcal)	CC	38.6 ± 7.3	34.1 ^{†cd} ± 9.7	35.7 ^{cd} ± 7.2	38.2 ^{bcd} ± 7.4	36.7 ± 1.0	T = 0.001
	WW	38.4 ± 7.4	32.8 ^{†ce} ± 7.8	32.7 ^{†ce} ± 4.9	32.8 ^{†ce} ± 6.8	34.2 ± 0.9	D = 0.001
	JC	36.5 ± 6.9	24.8 ^{†de} ± 5.9	24.3 ^{†de} ± 7.9	25.9 ^{†de} ± 7.9	27.9 ± 1.0	T x D = 0.001
	NS	38.5 ± 7.3	29.9 ^{†e} ± 5.3	31.0 ^{†e} ± 7.3	32.7 ^{†e} ± 8.7	33.0 ± 0.9	
	C	36.7 ± 7.0	37.1 ± 4.9	38.1 ± 5.5	38.7 ± 5.2	37.7 [†] ± 1.0	
	Mean	37.8 ± 7.1	31.5 ± 8.0	32.1 ± 7.7	33.3* ± 8.6		

Values are represented as means ± standard deviation except group means are ± standard error mean. n = 117; CC (n=22), WW (n=27), JC (n=24), NS (n=25), and C (n=19). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline $p < 0.05$ (univariate). † = significant diet effect $p < 0.05$ (univariate). ‡ = significant time effect from baseline $p < 0.05$ (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC ($p < 0.05$). b = significantly different than WW ($p < 0.05$). c = significantly different than JC ($p < 0.05$). d = significantly different than NS ($p < 0.05$). e = significantly different than C ($p < 0.05$). # = a trend toward significance from baseline $p > 0.05$ and $p < 0.1$ (post hoc LSD). f = a trend toward significance compared to CC ($p > 0.05$ and $p < 0.1$). g = a trend toward significance compared to WW ($p > 0.05$ and $p < 0.1$). h = a trend toward significance compared to JC ($p > 0.05$ and $p < 0.1$). i = a trend toward significance compared to NS ($p > 0.05$ and $p < 0.1$). j = a trend toward significance compared to C ($p > 0.05$ and $p < 0.1$).

$p=0.003$, NS $p<0.001$). CC ($7.1\pm7.6\%$) had a greater increase in percent protein intake at week 12 compared to WW (3.5 ± 4.5 , $p=0.032$), JC ($1.56.3$, $p=0.001$), and C ($-0.3\pm3.6\%$, $p<0.001$). However, NS had the greatest increase in percent intake of protein at week 12 ($8.9\pm6.3\%$). When looking at the percentage of carbohydrates of total kilocalories, CC had a significantly less percentage compared to baseline at weeks 8 ($p=0.045$) and 12 ($p=0.006$). Whereas, JC had a significantly greater percentage compared to baseline at weeks 4, 8, and 12 ($p<0.001$ at each time point). CC had a greater decrease in percent carbohydrates at weeks 12 compared to WW (2.2 ± 11.5 , $p=0.007$) and JC (9.2 ± 12.9 , $p<0.001$) and was the greatest decrease out of all the groups (CC $-6.7\pm10.9\%$, $p=0.006$). When assessing percentage of fat in total kilocalories, CC had a decrease in percent fat at week 4 ($p=0.026$), but it was not significant at weeks 8 and 12. WW, JC, and NS had a significant decrease in percent fat at weeks 4 (WW $p=0.002$, JC $p<0.001$, NS $p<0.001$), 8 (WW $p=0.002$, JC $p<0.001$, NS $p<0.001$), and 12 (WW $p=0.003$, JC $p<0.001$, NS $p=0.004$). Percent fat intake was significantly less in CC by week 12 when compared to JC ($p=0.001$). JC had the greatest decrease in percent fat at week 12 ($-10.6\pm10.1\%$).

Eating Satisfaction Survey

The Eating Satisfaction Survey was assessed at 0, 4, 8, and 12 weeks of intervention. An overall time (Wilks' Lambda $p<0.001$) effect was observed, though an overall time x diet interaction (Wilks' Lambda $p=0.119$) effect was not significant. As depicted in Table 7, for the variable of appetite, JC (-0.96 ± 1.87 , $p=0.005$) and C (-1.05 ± 1.28 , $p=0.008$) had a significant decrease from baseline at week 12. In the category of hunger, C had a significant decrease at week 12 (-1.05 ± 2.19 , $p=0.031$). The C group

also had a significant decrease from baseline at week 12 for the area of satisfied food (-0.90 ± 2.25 , $p=0.039$). For the variable of fullness, JC was significantly lower at week 12 (-1.04 ± 2.39 , $p=0.004$). In the category of energy, CC, WW, JC, and NS all had a time effect at weeks 4 (CC $p<0.001$; WW $p<0.001$; JC $p<0.001$; NS $p<0.001$), 8 (CC $p<0.001$; WW $p<0.001$; JC $p<0.001$; NS $p=0.001$), and 12 (CC 1.63 ± 1.84 , $p<0.001$; WW 1.44 ± 1.82 , $p<0.001$; JC 0.85 ± 2.25 , $p=0.024$; NS 1.18 ± 1.83 , $p=0.002$). CC had a significant increase in the area of energy compared to C (0.45 ± 1.90 , $p=0.041$), and WW had a trend toward a significant increase compared with C ($p=0.078$) at week 12. Additionally, in the area of quality, CC, WW, JC, and NS had a time effect at weeks 4 (CC $p<0.001$; WW $p<0.001$; JC $p<0.001$; NS $p<0.001$), 8 (CC $p<0.001$; WW $p<0.001$; JC $p<0.001$; NS $p<0.001$), and 12 (CC 1.81 ± 2.02 , $p<0.001$; WW 1.83 ± 1.94 , $p<0.001$; JC 2.26 ± 2.18 , $p<0.001$; NS 1.75 ± 2.05 , $p<0.001$). CC, WW, JC, and NS showed significant increases when compared to the C group (CC $p=0.002$; WW $p=0.001$; JC $p<0.001$; NS $p=0.002$). Therefore, we accept H_01 since statistically significant differences were observed among groups in macronutrient intake.

Physical Activity

Physical activity was assessed at 0, 4, 8, and 12 weeks by a seven day self-reported physical activity log and by the International Physical Activity Questionnaire (IPAQ). Analysis by MANOVA revealed an overall trend toward significance for time (Wilks' Lambda $p=0.061$) and no overall time x diet (Wilks' Lambda $p=0.247$) effect for physical activity. When looking at delta changes from baseline, CC had a trend toward a significant increase in low physical activity (MET 3.3) at week 12 ($p=0.077$). The C group had a

Table 7: Changes in eating satisfaction survey. Observed between groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C).

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Appetite	CC	5.40 ± 1.30	5.00 ± 1.40	5.10 ± 1.30	4.90 ± 1.30	5.11 ± 0.20	T = 0.001
	WW	5.20 ^{ci} ± 1.40	5.10 ± 1.30	5.20 ± 1.80	4.90 ± 1.50	5.11 ± 0.19	D = 0.511
	JC	6.00 ± 1.50	5.40 [#] ± 1.60	5.40 [#] ± 1.10	5.00 [‡] ± 1.70	5.47 ± 0.20	T x D = 0.899
	NS	5.60 ± 1.40	5.20 ± 1.60	5.50 ± 1.70	5.30 ± 1.70	5.40 ± 0.20	
	C	6.00 ± 1.30	5.20 [#] ± 1.30	5.70 ± 0.90	5.00 [‡] ± 1.00	5.45 ± 0.23	
	Mean	5.60 ± 1.40	5.20 ± 1.40	5.40 ± 1.40	5.00* ± 1.50		
Hunger	CC	4.70 ^e ± 1.30	4.30 ± 1.60	4.50 ± 1.20	4.30 ± 1.50	4.45 ± 0.22	T = 0.001
	WW	4.90 ^j ± 1.80	4.60 ± 1.50	4.60 ± 1.80	4.90 ± 1.50	4.73 ± 0.21	D = 0.222
	JC	5.50 ± 1.70	4.70 [#] ± 1.60	4.80 [#] ± 1.20	4.90 ± 1.60	4.99 ± 0.22	T x D = 0.814
	NS	5.00 ± 2.00	4.10 ^{‡i} ± 1.50	4.80 ± 1.70	4.50 ± 1.60	4.60 ± 0.21	
	C	5.80 ± 1.90	5.00 [#] ± 1.40	5.00 [#] ± 1.10	4.70 [‡] ± 1.70	5.11 ± 0.25	
	Mean	5.10 ± 1.80	4.50 ± 1.60	4.70 ± 1.40	4.70* ± 1.50		
Satisfied food	CC	6.00 ± 1.40	6.40 ± 1.40	6.20 ± 1.60	5.90 ± 1.40	6.11 ± 0.20	T = 0.022
	WW	6.50 ± 1.20	6.60 ± 1.20	6.60 ± 1.10	6.40 ^e ± 1.30	6.50 ± 0.19	D = 0.303
	JC	6.60 ± 1.70	6.60 ± 1.60	6.10 ± 1.30	6.00 [#] ± 1.60	6.34 ± 0.20	T x D = 0.824
	NS	6.00 ± 1.50	6.50 ± 1.60	6.00 ± 1.70	6.00 ± 1.50	6.14 ± 0.19	
	C	6.30 ± 2.10	6.10 ± 1.70	6.00 ± 1.20	5.40 [‡] ± 1.70	5.91 ± 0.23	
	Mean	6.30 ± 1.50	6.40 ± 1.50	6.20 ± 1.40	6.00* ± 1.50		
Fullness	CC	6.30 ± 1.40	6.30 ± 1.20	6.50 ± 1.30	6.10 ± 1.10	6.30 ± 0.17	T = 0.003
	WW	6.60 ± 1.10	6.30 ± 1.30	6.30 ± 1.20	6.00 ± 0.90	6.31 ± 0.17	D = 0.986
	JC	6.70 ± 1.50	6.50 ± 1.60	6.10 ± 1.50	5.60 [‡] ± 1.80	6.23 ± 0.17	T x D = 0.828
	NS	6.60 ± 1.60	6.50 ± 1.40	6.10 ± 1.40	6.10 ± 1.20	6.34 ± 0.17	
	C	6.50 ± 1.70	6.50 ± 1.80	6.00 ± 1.60	6.00 ± 1.20	6.21 ± 0.20	
	Mean	6.50 ± 1.40	6.40 ± 1.40	6.20 ± 1.40	6.00* ± 1.30		
Energy	CC	4.80 ± 1.50	6.60 ^{‡g} ± 1.60	6.40 [‡] ± 1.60	6.40 [‡] ± 1.40	6.06 ± 0.21	T = 0.001
	WW	4.60 ± 1.70	5.90 [‡] ± 1.30	6.30 [‡] ± 1.00	6.00 [‡] ± 1.10	5.71 ± 0.20	D = 0.001
	JC	5.00 ± 1.70	6.30 [‡] ± 1.30	6.30 [‡] ± 1.30	5.80 [‡] ± 1.80	5.84 ± 0.21	T x D = 0.229
	NS	4.90 ± 1.50	6.30 [‡] ± 1.40	6.00 [‡] ± 1.60	6.1 [‡] ± 1.40	5.81 ± 0.20	
	C	4.40 ± 1.60	4.80 ^{abcd} ± 1.80	5.00 ^{abcd} ± 1.50	4.80 ^{abcd} ± 1.40	4.71 [†] ± 0.24	
	Mean	4.70 ± 1.60	6.00 ± 1.60	6.10 ± 1.50	5.90* ± 1.50		
Quality	CC	4.20 ± 1.70	6.40 ^{‡c} ± 1.40	6.10 [‡] ± 1.60	6.00 [‡] ± 1.60	5.64 ± 0.21	T = 0.001
	WW	4.60 ± 1.80	6.60 [‡] ± 1.00	6.20 [‡] ± 1.10	6.40 [‡] ± 1.30	6.00 ± 0.20	D = 0.001
	JC	4.00 ± 1.60	7.10 [‡] ± 1.30	6.60 [‡] ± 1.80	6.30 [‡] ± 1.80	6.00 ± 0.21	T x D = 0.001
	NS	4.50 ± 1.50	6.90 [‡] ± 1.40	6.40 [‡] ± 1.50	6.20 [‡] ± 1.40	6.00 ± 0.20	
	C	4.80 ± 2.20	4.70 ^{abcd} ± 1.30	4.90 ^{abcd} ± 1.30	4.6 ^{abcd} ± 1.30	4.73 [†] ± 0.24	
	Mean	4.40 ± 1.70	6.40 ± 1.50	6.10 ± 1.60	6.00* ± 1.60		

Values are represented as means ± standard deviation except group means are ± standard error mean. n = 131; CC (n=27), WW (n=29), JC (n=27), NS (n=28), and C (n=20). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p < 0.05 (univariate). † = significant diet effect p < 0.05 (univariate). ‡ = significant time effect from baseline p < 0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC (p < 0.05). b = significantly different than WW (p < 0.05). c = significantly different than JC (p < 0.05). d = significantly different than NS (p < 0.05). e = significantly different than C (p < 0.05). # = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). f = a trend toward significance compared to CC (p > 0.05 and p < 0.1). g = a trend toward significance compared to WW (p > 0.05 and p < 0.1). h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). i = a trend toward significance compared to NS (p > 0.05 and p < 0.1). j = a trend toward significance compared to C (p > 0.05 and p < 0.1).

downward trend at week 4 ($p=0.053$) and had a significant decrease in low physical activity at week 8 ($p=0.008$). CC had a greater increase in low physical activity ($993\pm3,355$ MET-min/wk) when compared with JC ($-589\pm2,797$, $p=0.047$) and C ($-948\pm3,962$ MET-min/wk, $p=0.030$) at week 12. Analysis of moderate physical activity revealed an upward trend at week 4 ($p=0.070$) and a significant increase in the CC group at week 8 ($2,198\pm5,277$ MET-min/wk, $p=0.001$). JC also had an upward trend at week 4 ($p=0.067$), a significant decrease in moderate physical activity at weeks 4 ($p=0.032$) and 8 ($p=0.006$). Further, at week 8, CC had significantly greater increases compared to all other groups and NS had a significant decrease at week 8 ($p=0.042$) for moderate physical activity. The CC group had the greatest increase at week 8 compared to all other groups (CC $2,198\pm5,277$; WW $-240\pm1,572$, $p=0.006$; JC $-518\pm2,477$, $p=0.003$; NS $-1,272\pm2,250$, $p<0.001$; C $-2,205\pm3,492$ MET-min/wk, $p<0.001$). WW also experienced a significant increase compared with the C group ($p=0.048$) at week 8. When assessing vigorous physical activity CC showed an upward trend toward significance ($p=0.069$) at week 4. NS also had a significant increase at week 4 ($p=0.039$). As shown in Figure 6, CC had a significant increase in total physical activity (low + moderate + vigorous) at weeks 4 ($4,127\pm11,151$, $p=0.018$) and week 8 ($3,800\pm8,668$ MET-min/wk, $p=0.012$). NS also had an increase at week 4 ($3,630\pm12,515$, $p=0.033$), and the C group experienced a significant decrease at week 8 ($p=0.038$). When assessing physical activity relating to transportation, the CC group had an upward trend at week 12 ($p=0.054$). The C group had a significant decrease at weeks 4 ($p=0.033$), 8 ($p=0.010$), and 12 ($p=0.038$). When looking at physical activity relating to household activities, CC had an upward trend at week 4 ($p=0.064$) and

Table 8: Changes in international physical activity questionnaire. Observed between groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C).

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Low PA^k (MET-min/wk)	CC	577 ^{ce} ± 783	946 ^c ± 459	1,325 ± 2,273	1,570 ^f ± 3,454	1,105 ± 313	T = 0.447
	WW	1,037 ^{ce} ± 1,702	1,081 ^c ± 1,804	1,183 ± 1,858	873 ± 1,143	1,044 ± 296	D = 0.026
	JC	2,469 ^f ± 2,819	2,610 ^d ± 3,450	1,943 ^d ± 2,319	1,880 ± 2,281	2,226 ± 313	T x D = 0.150
	NS	1,288 ^e ± 1,341	1,386 ± 1,844	816 ± 715	1,619 ± 2,779	1,277 ± 307	
	C	2,943 ± 4,093	1,733 ^f ± 2,166	1,204 ^z ± 1,333	1,995 ± 2,781	1,991 [†] ± 387	
	Mean	1,553 ± 2,374	1,523 ± 2,222	1,306 ± 1,839	1,541 ± 2,554		
Moderate PA (MET-min/wk)	CC	1,267 ± 1,382	2,374 [#] ± 3,612	3,464 ^{†bcd} ± 5,376	2,283 ± 2,654	2,347 ± 463	T = 0.279
	WW	1,681 ± 1,545	1,931 ± 2,245	1,441 ± 1,346	1,173 ^e ± 1,497	1,557 ± 438	D = 0.303
	JC	1,984 ± 2,892	3,104 [#] ± 3,766	1,466 ± 1,527	2,588 ± 3,374	2,286 ± 463	T x D = 0.027
	NS	2,413 ± 2,322	2,987 ± 4,012	1,142 ^z ± 1,151	1,689 [†] ± 1,453	2,058 ± 454	
	C	4,165 ^{abci} ± 6,317	2,543 ^z ± 3,767	1,960 ^z ± 3,399	3,764 ± 8,704	3,108 ± 572	
	Mean	2,154 ± 3,112	2,578 ± 3,469	1,873 ± 3,033	2,162 ± 3,887		
Vigorous PA (MET-min/wk)	CC	1,038 ± 3,945	3,689 [#] ± 9,311	1,894 ± 5,068	1,457 [†] ± 3,036	2,020 ± 578	T = 0.068
	WW	200 ± 772	1,193 ± 3,304	1,065 ± 3,686	642 ± 2,292	775 ± 547	D = 0.500
	JC	1,452 ± 5,296	1,523 ± 3,970	2,971 [†] ± 9,121	1,240 ± 4,114	1,796 ± 578	T x D = 0.794
	NS	347 ± 784	3,305 ^z ± 11,752	516 ± 2,292	923 ± 1,392	1,273 ± 567	
	C	938 ± 3,210	1,840 ± 4,571	913 ± 3,483	75 ± 310	941 ± 714	
	Mean	767 ± 3,258	2,325 ± 7,473	1,495 ± 5,336	920 ± 2,660		
Total PA (MET-min/wk)	CC	2,882 ^e ± 4,573	7,009 ^z ± 10,442	6,682 ^{†d} ± 9,190	5,310 ± 8,185	5,471 ± 1,083	T = 0.117
	WW	2,919 ^e ± 2,435	4,205 ± 4,360	3,689 ± 5,376	2,689 ± 4,062	3,375 ± 1,025	D = 0.351
	JC	5,678 ± 9,861	6,972 ± 9,457	6,192 [†] ± 10,402	5,551 ± 8,064	6,098 ± 1,083	T x D = 0.380
	NS	4,048 [†] ± 3,256	7,876 ^z ± 14,212	2,474 ± 3,354	4,231 ± 4,542	4,608 ± 1,062	
	C	8,046 ± 10,639	6,116 ± 7,932	4,166 ^z ± 7,459	5,834 ± #####	6,040 ± 1,339	
	Mean	4,426 ± 6,721	6,374 ± 9,819	4,635 ± 7,586	4,590 ± 7,218		
Job PA (MET-min/wk)	C	593 ± 1,342	323 ^d ± 707	1,219 ± 2,619	1,229 ± 3,411	841 ± 563	T = 0.455
	WW	862 ± 1,686	1,297 ± 2,478	1,051 ± 2,526	637 ^e ± 1,377	962 ± 533	D = 0.233
	JC	2,917 ± 9,996	3,241 ± 8,242	1,519 ± 2,221	1,339 ± 2,501	2,254 ± 563	T x D = 0.540
	NS	1,532 ± 1,871	2,261 ± 4,273	424 ^e ± 642	1,309 ± 2,175	1,381 ± 553	
	C	2,443 ± 4,966	2,240 ± 4,204	2,202 ± 5,450	2,454 ± 5,192	2,335 ± 697	
	Mean	1,593 ± 5,086	1,835 ± 4,724	1,205 ± 2,834	1,298 ± 2,965		
Transportation PA (MET-min/wk)	CC	199 ^{ce} ± 386	453 ± 575	722 ± 2,553	785 ^f ± 1,933	540 ± 156	T = 0.427
	WW	361 ^{eh} ± 871	365 ^c ± 758	178 ^c ± 290	274 ^c ± 470	294 ± 148	D = 0.057
	JC	951 ^d ± 1,373	814 ^d ± 1,350	741 ± 974	899 [†] ± 1,312	851 ± 156	T x D = 0.164
	NS	254 ^e ± 367	356 ± 646	265 ± 389	343 ± 592	304 ± 153	
	C	1,339 ± 2,857	580 ^z ± 848	212 ^z ± 380	558 ^z ± 923	672 ± 193	
	Mean	560 ± 1,354	504 ± 880	432 ± 1,281	564 ± 1,182		
House PA (MET-min/wk)	CC	985 ^e ± 1,361	1,959 [#] ± 3,561	2,602 ^{†bcde} ± 3,582	1,713 ± 2,063	1,815 ± 291	T = 0.527
	WW	1,175 ^e ± 890	1,435 ± 1,453	1,027 ± 889	726 ^{†j} ± 581	1,091 ± 275	D = 0.232
	JC	1,144 ^e ± 1,252	1,530 ± 1,929	948 ± 1,015	1,792 ± 2,729	1,354 ± 291	T x D = 0.044
	NS	1,706 ± 2,127	1,481 ± 2,085	736 [#] ± 713	1,267 ± 1,191	1,297 ± 285	
	C	2,824 ± 5,369	1,844 ± 2,662	1,188 ^z ± 1,821	1,981 ± 3,914	1,959 ± 360	
	Mean	1,468 ± 2,427	1,630 ± 2,378	1,297 ± 1,995	1,441 ± 2,218		
Recreation PA (MET-min/wk)	CC	1,104 ± 3,954	4,274 ^z ± 9,338	2,138 ± 5,028	1,583 ± 2,447	2,275 ± 523	T = 0.101
	WW	521 ± 1,010	1,108 ± 2,915	1,433 ± 3,722	1,051 ± 2,420	1,028 ± 495	D = 0.415
	JC	962 ± 1,157	1,681 ± 2,248	3,218 [#] ± 9,415	1,683 ± 4,282	1,886 ± 523	T x D = 0.596
	NS	557 ± 1,006	3,580 ± 11,648	1,049 ± 2,570	1,313 ± 1,649	1,625 ± 513	
	C	1,439 ± 3,567	1,452 ^z ± 4,082	565 ± 689	842 ± 2,118	1,074 ± 646	
	Mean	867 ± 2,369	2,466 ± 7,265	1,750 ± 5,325	1,321 ± 2,732		

Table 8: Continued

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Sit PA (MET-min/wk)	CC	1,258 ^g ± 589	1,045 ± 352	1,127 ^h ± 657	1,063 ± 666	1,124 ± 94	T = 0.002
	WW	1,351 ± 713	1,061 ^h ± 526	1,003 ^{td} ± 432	1,042 ^h ± 521	1,114 ± 89	D = 0.272
	JC	1,321 ⁱ ± 660	1,229 ± 1,115	1,227 ± 634	1,263 ± 559	1,260 ± 94	T x D = 0.605
	NS	1,341 ± 614	1,142 ± 582	1,434 ± 753	1,281 ± 476	1,300 ± 92	
	C	1,701 ± 1,067	1,214 ^h ± 648	1,277 ± 640	1,321 ^h ± 772	1,378 ± 116	
	Mean	1,371 ± 719	1,131 ± 685	1,206 ± 636	1,182 ± 593		

Values are represented as means±standard deviation except group means are ±standard error mean. n = 125; CC (n=26), WW (n=29), JC (n=26), NS (n=27), and C (n=17). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p<0.05 (univariate). † = significant diet effect p<0.05 (univariate). ‡ = significant time effect from baseline p<0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC (p < 0.05). b = significantly different than WW (p < 0.05). c = significantly different than JC (p < 0.05). d = significantly different than NS (p < 0.05). e = significantly different than C (p < 0.05). # = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). f = a trend toward significance compared to CC (p > 0.05 and p < 0.1). g = a trend toward significance compared to WW (p > 0.05 and p < 0.1). h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). i = a trend toward significance compared to NS (p > 0.05 and p < 0.1). j = a trend toward significance compared to C (p > 0.05 and p < 0.1). k = physical activity.

a significant increase at week 8 (1,618±3,921 MET-min/wk, p=0.002). NS had a downward trend though at week 8 (p=0.057), and C had a significant decrease at week 8 (p=0.011) in household related physical activity. CC had a greater increase compared with all other groups (CC 1,618±3,921; WW -147±1,150, p=0.014, JC -195±1,277, p=0.014; NS -969±2,257, p<0.001; C -1,636±3,785 MET-min/wk p<0.001) at week 8 in the area of household related physical activity. CC and NS also had significant increases in physical activity relating to recreational activities at week 4 (CC 3,170±10,322, p=0.031; NS 3,023±11,544 MET-min/wk, p=0.036), and JC experienced an upward trend at week 8 (p=0.055). In the area of sitting physical activity, WW had a downward trend at week 4 (p=0.052) and a significant decrease at weeks 8 (p=0.015) and 12 (p=0.045). The C group also had a significant decrease at weeks 4 (p=0.013) and 8 (p=0.023) as well as a downward trend at week 12 (p=0.059).

Physical activity was also assessed in the CC group by recording number of steps per day via a pedometer. The average number of steps from baseline to 12 weeks for the CC group was 8,907±2,366 steps. All participants were sedentary at baseline, which was

defined as not participating in a planned exercise program three months prior to the study and to not have exercised for more than 30 minutes a day on three or more days of the week. There were increases in physical activity in the CC group which were monitored by a required 75% compliance to the exercise protocol vs a recommended walking program in WW, JC, and NS. Due to changes seen in a variety of areas of physical activity, we accept Ho2 since statistically significant differences were observed among groups in physical activity levels.

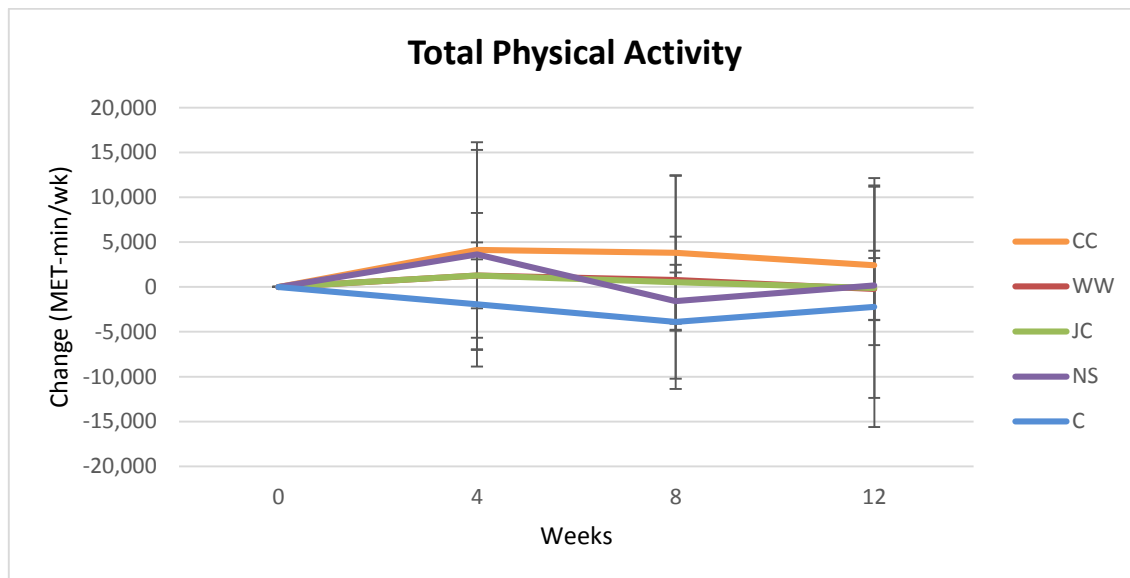


Figure 6: Changes from baseline in total physical activity over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. n=125.

Body Composition

Total weight, body mass index (BMI), and resting energy expenditure (REE) were assessed by ANOVA at 0, 4, 8, and 12 weeks. There was a significant overall time (Wilks' Lambda $p<0.001$) and time x diet (Wilks' Lambda $p<0.001$) effect for total weight. Table 9 shows that CC, WW, JC, and NS all had a significant decrease in total weight at weeks 4, 8, and 12 (CC -4.3 ± 4.3 , WW -4.4 ± 3.5 , JC -5.3 ± 3.8 , NS -5.2 ± 4.5 kg, $p<0.001$ for all groups at all three time points). At week 12, CC, WW, JC, and NS had a significantly greater decrease in weight compared to C (0.1 ± 3.1 kg; $p<0.001$ for all groups), which is depicted in Figure 7.

There was also an overall time (Wilks' Lambda $p<0.001$) effect and time x diet (Wilks' Lambda $p=0.044$) effect for BMI. Post hoc LSD analysis revealed a significant time effect from baseline for CC, WW, JC, NS, and C at weeks 4, 8, and 12 (CC -4.0 ± 1.7 , WW -4.4 ± 3.3 , JC -4.4 ± 1.6 , NS -4.3 ± 1.6 , C -2.4 ± 1.1 kg/m²; $p<0.001$ for all groups at each of the three time points). At week 12, though, CC ($p=0.008$), WW ($p=0.001$), JC ($p=0.001$), and NS ($p=0.001$) had a significantly lower BMI compared to the C group.

Resting energy expenditure (REE) was assessed as total kilocalories per day as well as total kilocalories per kilogram per day. When looking at REE represented as kcal/day, there was a significant time (Wilks' Lambda $p<0.001$) effect though no time x diet (Wilks' Lambda $p=0.287$) effect. CC and WW experienced a significant decrease in REE from baseline at weeks 4 (CC $p=0.005$, WW $p<0.001$), 8 (CC $p=0.048$, WW $p<0.001$) and 12 (CC -101.7 ± 170.4 , $p=0.004$; WW -108.0 ± 159.4 kcal/day, $p<0.002$), JC and NS had a significant decrease at week 4 (JC $p=0.020$, NS $p=0.025$) and a trend at week

8 (JC $p=0.060$, NS $p=0.081$). Also at week 12, CC ($p=0.011$) and WW ($p=0.008$) were significantly lower than C.

Table 9: Changes in weight, body mass index, and resting energy expenditure. Observed between groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C)

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Total Weight (kg)	CC	90.7 ± 13.6	88.4 [‡] ± 14.0	87.2 ^{‡j} ± 13.9	86.4 [‡] ± 14.1	88.2 ± 2.7	T = 0.001
	WW	91.1 ± 14.4	88.6 [‡] ± 14.7	87.5 ^{‡j} ± 14.8	86.8 ^{‡j} ± 14.3	88.5 ± 2.7	D = 0.263
	JC	91.0 ± 14.6	88.1 [‡] ± 14.2	86.8 ^{‡j} ± 14.5	85.7 ^{‡e} ± 14.5	87.9 ± 2.8	T X D = 0.001
	NS	96.8 ± 15.9	93.7 [‡] ± 16.1	92.5 [‡] ± 16.4	91.7 [‡] ± 16.6	93.7 ± 2.8	
	C	95.0 ± 14.2	94.9 ± 13.4	94.8 [‡] ± 13.3	95.1 ± 13.4	95.0 ± 3.3	
	Mean	92.8 ± 14.6	90.5 ± 14.7	89.4 ± 14.8	88.8* ± 14.9		
BMI (kg/m ²)	CC	34.9 ± 5.9	31.7 [‡] ± 5.8	31.3 ^{‡j} ± 5.7	30.9 ^{‡e} ± 5.8	32.2 ± 1.0	T = 0.001
	WW	34.2 ⁱ ± 6.4	30.5 ^{‡de} ± 5.2	30.1 ^{‡de} ± 5.2	29.8 ^{‡de} ± 5.1	31.1 ± 1.0	D = 0.126
	JC	35.1 ± 4.5	31.5 ^{‡j} ± 4.1	31.1 ^{‡e} ± 4.2	30.7 ^{‡e} ± 4.2	32.1 ± 1.0	T X D = 0.001
	NS	36.9 ± 5.4	33.3 [‡] ± 5.4	32.8 [‡] ± 5.5	32.6 [‡] ± 5.7	33.9 ± 1.0	
	C	36.6 ± 5.2	34.1 [‡] ± 4.9	34.2 [‡] ± 5.0	34.2 [‡] ± 5.1	34.8 ± 1.2	
	Mean	35.5 ± 5.6	32.1 ± 5.2	31.7 ± 5.3	31.5* ± 5.3		
REE (kcal/d)	CC	1,501.0 ± 222.3	1,418.0 [‡] ± 244.4	1,435.7 ^{‡j} ± 203.3	1,399.2 [‡] ± 242.3	1,438.5 ± 37.0	T = 0.001
	WW	1,470.9 ± 218.1	1,357.5 [‡] ± 249.8	1,340.6 ^{‡j} ± 210.7	1,362.9 [‡] ± 217.0	1,383.0 ± 37.0	D = 0.640
	JC	1,412.7 ± 243.7	1,341.3 [‡] ± 209.3	1,348.5 ^{‡j} ± 221.6	1,385.4 ± 217.7	1,372.0 ± 38.3	T X D = 0.001
	NS	1,500.4 ± 220.2	1,432.8 [‡] ± 191.8	1,442.0 [‡] ± 180.4	1,457.7 ± 256.6	1,458.2 ± 37.6	
	C	1,416.9 ± 224.7	1,396.6 ± 190.4	1,433.5 ± 206.4	1,455.6 ± 245.7	1,425.6 ± 44.5	
	Mean	1,463.7 ± 225.7	1,389.1 ± 220.4	1,398.2 ± 206.8	1,409.3* ± 235.3		
REE (kcal/kg/d)	CC	16.63 ^{ghi} ± 1.69	16.08 ^{‡de} ± 1.62	16.58 ^{beh} ± 1.55	16.26 ± 1.65	16.39 ± 0.29	T = 0.008
	WW	16.27 ^e ± 1.97	15.43 [‡] ± 2.30	15.45 [‡] ± 1.85	15.82 ± 1.91	15.74 ± 0.29	D = 0.365
	JC	15.64 ± 2.11	15.32 ± 1.55	15.65 ± 1.93	16.33 ^{‡j} ± 2.05	15.73 ± 0.30	T X D = 0.081
	NS	15.69 ± 2.28	15.48 ± 1.77	15.85 ± 2.05	16.05 ± 2.11	15.77 ± 0.29	
	C	14.99 ± 1.74	14.81 ± 1.63	15.22 ± 1.88	15.35 ± 1.93	15.09 ± 0.35	
	Mean	15.91 ± 2.03	15.47 ± 1.82	15.79 ± 1.88	16.00* ± 1.93		

Values are represented as means±standard deviation except group means are ±standard error mean. n = 133; CC (n=29), WW (n=29), JC (n=27), NS (n=28), and C (n=20). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline $p < 0.05$ (univariate). † = significant diet effect $p < 0.05$ (univariate). ‡ = significant time effect from baseline $p < 0.05$ (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC ($p < 0.05$). b = significantly different than WW ($p < 0.05$). c = significantly different than JC ($p < 0.05$). d = significantly different than NS ($p < 0.05$). e = significantly different than C ($p < 0.05$). # = a trend toward significance from baseline $p > 0.05$ and $p < 0.1$ (post hoc LSD). f = a trend toward significance compared to CC ($p > 0.05$ and $p < 0.1$). g = a trend toward significance compared to WW ($p > 0.05$ and $p < 0.1$). h = a trend toward significance compared to JC ($p > 0.05$ and $p < 0.1$). i = a trend toward significance compared to NS ($p > 0.05$ and $p < 0.1$). j = a trend toward significance compared to C ($p > 0.05$ and $p < 0.1$).

When assessed as kcal/kg/day, there was an overall time (Wilks' Lambda $p=0.006$) effect but no time x diet (Wilks' Lambda $p=0.425$) effect. CC had a trend toward a significant decrease at week 4 ($p=0.091$) but not at weeks 8 or 12. However, WW still had a significantly lower REE at weeks 4 ($p=0.011$) and 8 ($p=0.029$). JC also had a trend

toward a significant increase in REE at week 12 ($p=0.077$). Also at week 12, WW had a significantly lower REE compared to JC ($p=0.036$), and CC expressed a trend toward being significantly lower than JC ($p=0.051$). All groups maintained relative REE, and the average change in REE for the groups at week 12 were CC -0.37 ± 1.85 , $p=0.322$; WW -0.45 ± 1.80 , $p=0.228$; JC 0.69 ± 2.13 , $p=0.077$; NS 0.36 ± 2.20 , $p=0.341$; C 0.36 ± 2.08 kcal/kg/day, $p=0.424$, shown in Figure 8.

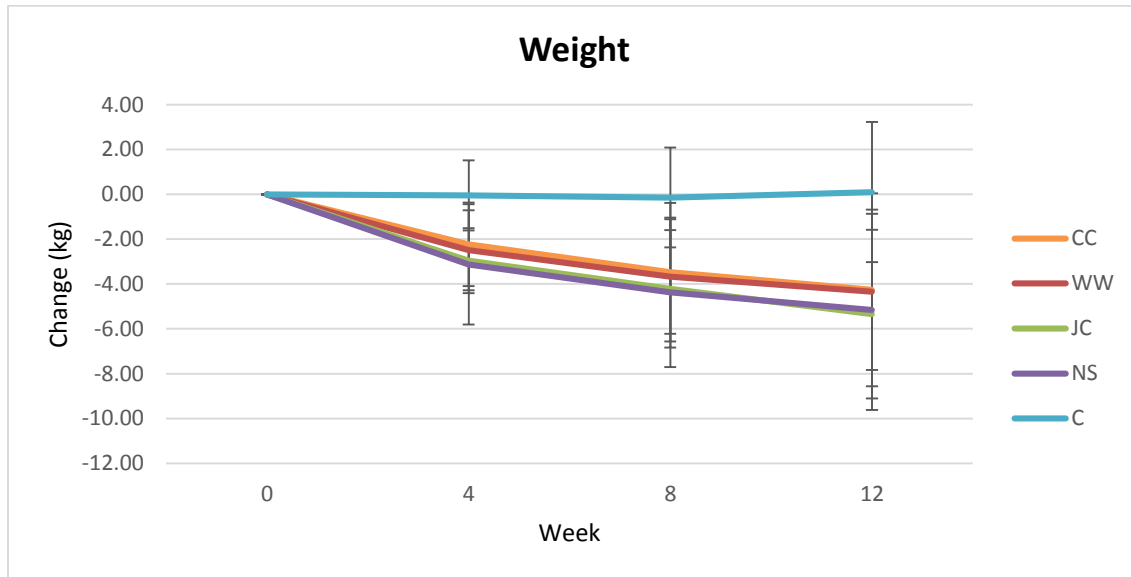


Figure 7: Changes from baseline in total weight over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. $n=133$.

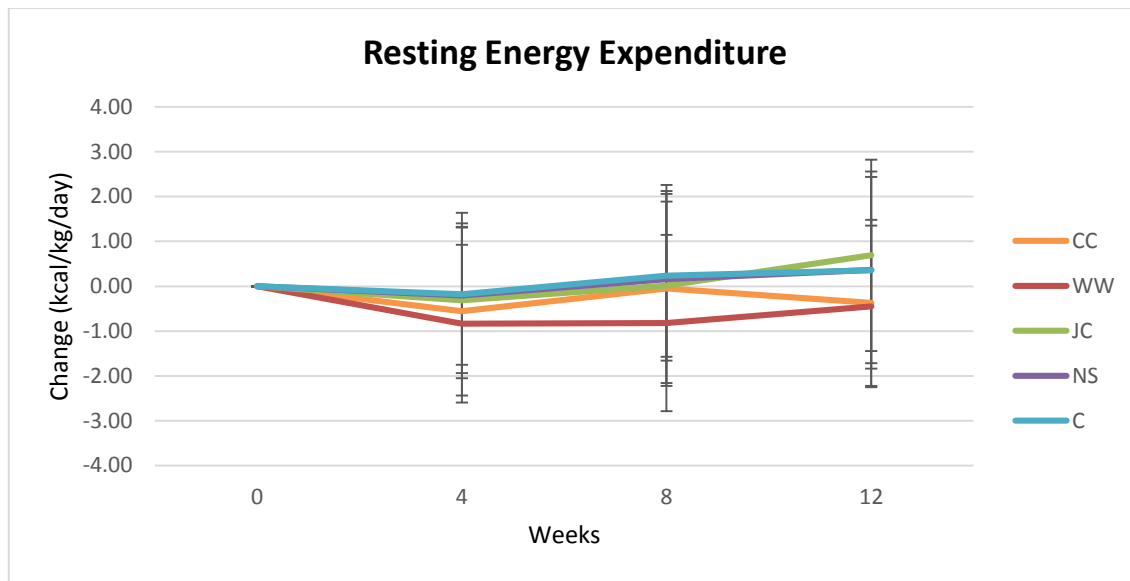


Figure 8: Changes from baseline in resting energy expenditure over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. n=133.

Dual Energy X-Ray Absorptiometry Measurements

Total scanned mass, fat mass, fat-free mass, and body fat percentage are presented in Table 10. MANOVA analysis of the body composition data revealed an overall time (Wilks' Lambda $p < 0.001$) and time by diet (Wilks' Lambda $p < 0.001$) effect. As seen in Table 8, when analyzed by MANOVA univariate there was a significant time ($p < 0.001$) and time x diet ($p < 0.001$) effect for total scanned mass (-3.8 ± 4.1 kg), fat mass (-2.5 ± 3.2 kg), fat-free mass (-1.3 ± 2.4 kg), and body fat percentage ($-1.1 \pm 2.6\%$). CC, WW, JC, and NS experienced a significant decrease in total scanned mass at weeks 4, 8, and 12 (WW - 4.0 ± 4.4 , NS -4.8 ± 4.0 kg; $p < 0.001$ for all groups at each time point) and fat mass at weeks

Table 10: Changes in body composition. Observed between groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C).

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Total Mass (kg)	CC	84.2 ± 13.1	82.2 [‡] ± 13.5	81.0 ^{†j} ± 13.4	80.2 ^{†e} ± 13.5	81.9 ± 2.6	T = 0.001
	WW	84.5 ± 14.2	82.2 [‡] ± 14.3	81.2 ^{†j} ± 14.3	80.5 ^{†j} ± 13.9	82.1 ± 2.6	D = 0.263
	JC	84.8 ± 14.0	81.7 [‡] ± 13.5	80.6 ^{†j} ± 13.9	79.5 ^{†e} ± 14.0	81.7 ± 2.7	T X D = 0.001
	NS	90.1 ± 15.3	87.2 [‡] ± 15.7	86.0 [‡] ± 16.0	85.3 [‡] ± 16.2	87.1 ± 2.7	
	C	88.4 ± 13.6	88.3 ± 12.9	88.5 ± 12.9	88.5 ± 12.8	88.4 ± 3.1	
	Mean	86.3 ± 14.1	84.1 ± 14.1	83.1 ± 14.3	82.5* ± 14.4		
Fat Mass (kg)	CC	38.6 ± 8.0	36.6 ^{†j} ± 8.7	35.2 ^{†de} ± 8.4	34.8 ^{†de} ± 8.9	36.3 ± 1.7	T = 0.001
	WW	37.6 ^d ± 9.0	36.8 [‡] ± 9.6	35.8 ^{†ei} ± 9.1	35.4 ^{†ei} ± 9.4	36.4 ± 1.7	D = 0.126
	JC	39.6 ± 7.7	37.8 [‡] ± 7.7	36.4 ^{†j} ± 7.9	36.1 ^{†j} ± 7.7	37.4 ± 1.7	T X D = 0.001
	NS	42.3 ± 10	40.8 [‡] ± 11	40.3 [‡] ± 11.0	40.0 [‡] ± 11	40.8 ± 1.7	
	C	41.1 ± 9.1	41.1 ± 8.2	41.3 ± 8.0	41.1 ± 8.3	41.1 ± 2.0	
	Mean	39.7 ± 8.8	38.4 ± 9.2	37.6 ± 9.2	37.2* ± 9.3		
Fat Free Mass (kg)	CC	45.6 ± 6.5	45.6 ± 6.4	45.8 ± 6.8	45.4 ± 6.3	45.6 ± 1.3	T = 0.001
	WW	46.9 ± 7.0	45.4 [‡] ± 6.8	45.4 [‡] ± 7.2	45.1 [‡] ± 6.6	45.7 ± 1.3	D = 0.640
	JC	45.2 ± 7.8	43.9 [‡] ± 7.0	44.3 [‡] ± 7.3	43.4 ^{†j} ± 7.6	44.2 ± 1.3	T X D = 0.001
	NS	47.8 ± 6.7	46.4 [‡] ± 6.7	45.7 [‡] ± 7.0	45.3 [‡] ± 6.9	46.3 ± 1.3	
	C	47.3 ± 7.7	47.2 ± 7.3	47.2 ± 7.5	47.5 ± 7.2	47.3 ± 1.5	
	Mean	46.5 ± 7.1	45.6 ± 6.8	45.6 ± 7.1	45.2* ± 6.9		
Body Fat (%)	CC	45.6 ± 3.7	44.1 ^{†j} ± 4.7	43.1 ^{†deh} ± 4.9	42.9 ^{†deh} ± 5.4	43.9 ± 0.9	T = 0.001
	WW	44.1 ^{†j} ± 4.8	44.3 ± 5.4	43.8 ^{†j} ± 5.5	43.5 ^{†j} ± 5.7	43.9 ± 0.9	D = 0.117
	JC	46.6 ± 3.9	46.0 ± 4.0	44.9 [‡] ± 4.2	45.2 [‡] ± 4.3	45.7 ± 0.9	T X D = 0.001
	NS	46.5 ± 4.6	46.2 ± 5.1	46.3 ± 5.7	46.3 ± 5.2	46.3 ± 0.9	
	C	46.3 ± 5.2	46.4 ± 4.5	46.6 ± 4.5	46.3 ± 4.5	46.4 ± 1.0	
	Mean	45.8 ± 4.5	45.3 ± 4.8	44.8 ± 5.2	44.7* ± 5.2		

Values are represented as means±standard deviation except group means are ±standard error mean. n = 133; CC (n=29), WW (n=29), JC (n=27), NS (n=28), and C (n=20). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p<0.05 (univariate). † = significant diet effect p<0.05 (univariate). ‡ = significant time effect from baseline p<0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC (p < 0.05). b = significantly different than WW (p < 0.05). c = significantly different than JC (p < 0.05). d = significantly different than NS (p < 0.05). e = significantly different than C (p < 0.05). # = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). f = a trend toward significance compared to CC (p > 0.05 and p < 0.1). g = a trend toward significance compared to WW (p > 0.05 and p < 0.1). h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). i = a trend toward significance compared to NS (p > 0.05 and p < 0.1). j = a trend toward significance compared to C (p > 0.05 and p < 0.1).

4, 8, and 12 (CC -3.8±4.0, WW -2.2±2.6, JC -3.5±3.3, NS -2.3±2.5 kg, p<0.001 for all groups at each time point except week 4 for WW p=0.025). At the end of the 12 weeks, CC (-4.0±4.4, p<0.001) and JC (-5.3±3.7 kg, p<0.001) had a significantly greater decrease in total mass compared to the C group (0.1±4.1 kg), seen in Figure 9. WW, JC, and NS

had a significant loss in fat-free mass at weeks 4, 8, and 12 (WW -1.8 ± 2.3 , JC -1.8 ± 2.1 , NS -2.4 ± 2.2 kg, $p < 0.001$ at each time point for WW, JC, and NS, except JC at week 8 $p = 0.007$), presented in Figure 11. Further, in Figure 12, CC had a significant decrease in body fat percentage at weeks 4 ($p < 0.001$), 8 ($p < 0.001$), and 12 ($p < 0.001$), and JC also did at weeks 8 ($p < 0.001$) and 12 ($-1.4 \pm 2.4\%$, $p = 0.004$). Even though JC had a significant decrease in body fat percentage, at week 12, CC had a significantly greater decrease in body fat percentage compared to WW ($p = 0.001$), JC ($p = 0.038$), NS

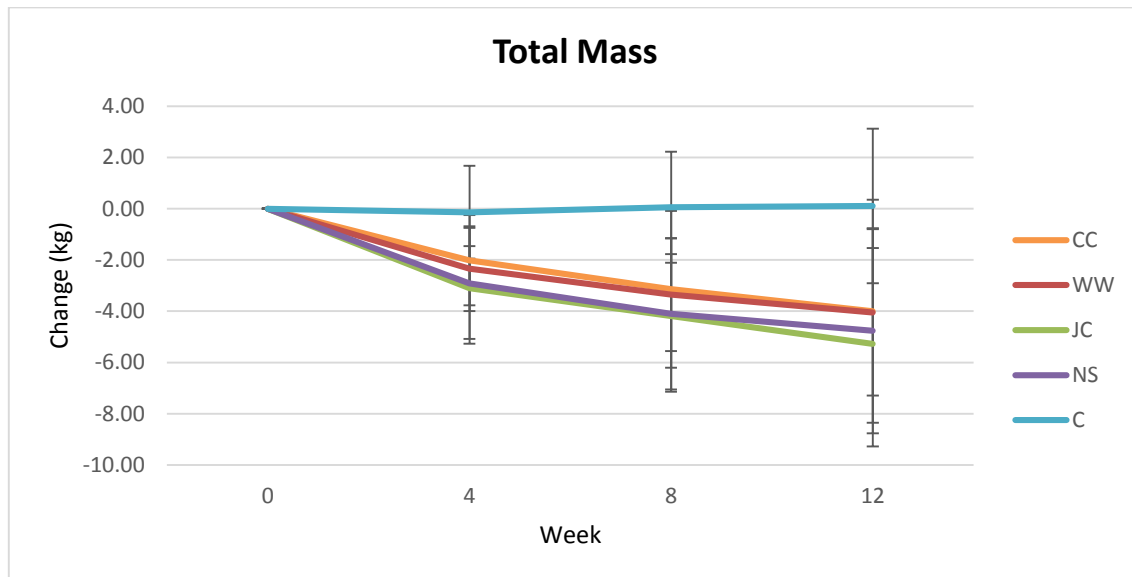


Figure 9: Changes from baseline in total scanned mass over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. $n = 133$.

($p<0.001$), and C ($p<0.001$). JC had a trend toward significance compared to NS at weeks 8 ($p=0.074$) and 12 ($p=0.071$). CC had the greatest decrease in fat-mass (-3.8 ± 4.0 kg, $p<0.001$), shown in Figure 10 and body fat percentage ($-2.7\pm3.4\%$, $p<0.001$), while maintaining fat-free mass (-0.2 ± 2.0 kg, $p=0.631$) at week 12. Therefore, we can accept H_03 since statistically significant differences were observed among groups in body composition related variables.

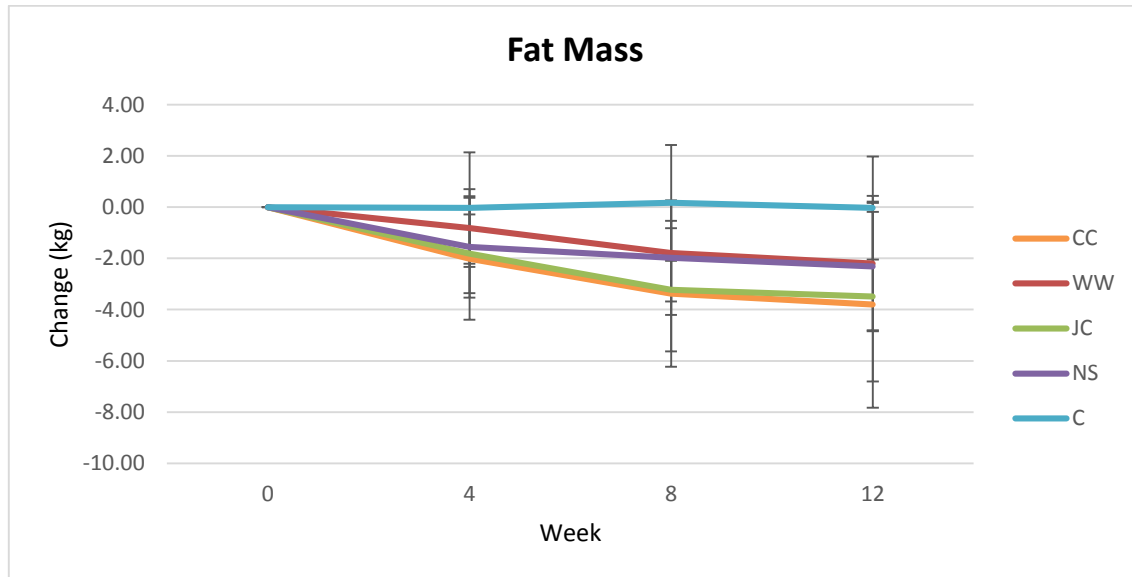


Figure 10: Changes from baseline in fat mass over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. n=133.

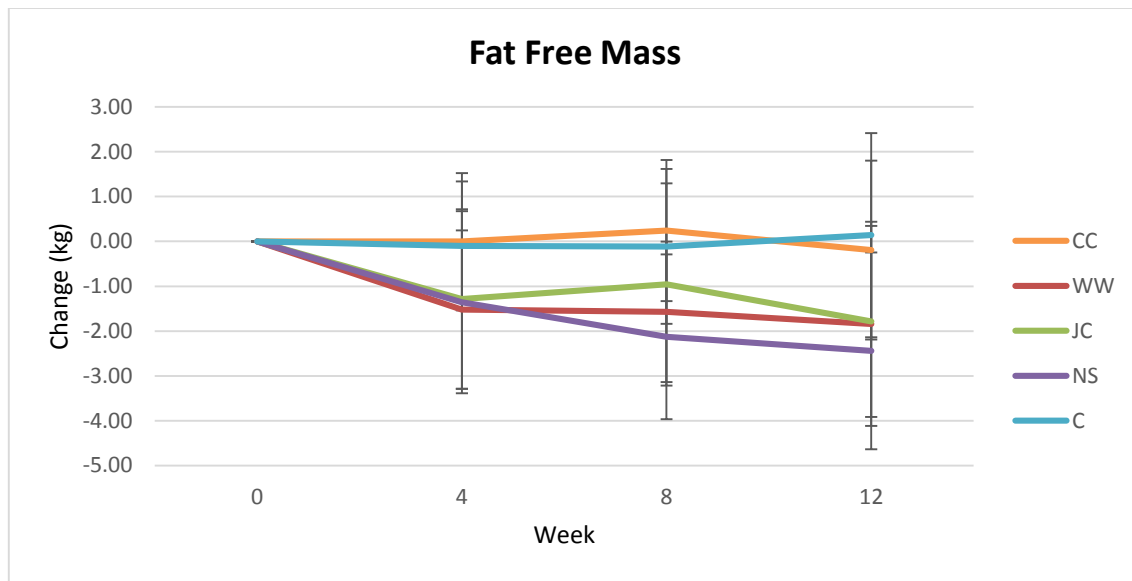


Figure 11: Changes from baseline in fat free mass over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. n=133.

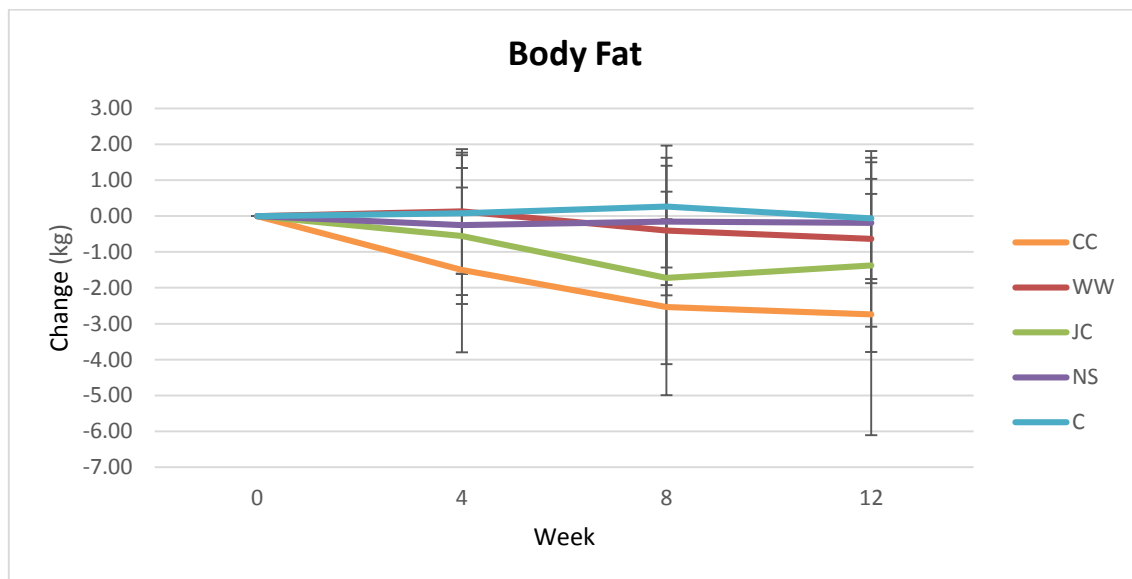


Figure 12: Changes from baseline in percent body fat over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. n=133.

Table 11: Changes in anthropometric measurements. Observed between groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C).

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Waist Circumference (cm)	CC	94.3 ⁱ ± 12	92.8 ^{#i} ± 12	91.4 ^{†‡i} ± 11	91.5 ^{†‡i} ± 11.8	92.5 ± 2.00	T = 0.001
	WW	96.6 ± 12	93.4 ^{‡i} ± 11.0	93 ^{‡i} ± 11	92.4 ^{†‡i} ± 9.8	93.8 ± 2.00	D = 0.211
	JC	96.8 ± 11.7	94.2 [‡] ± 11	93.9 [‡] ± 10	93.1 ^{†‡i} ± 10.5	94.5 ± 3.10	T X D = 0.007
	NS	99.4 ± 10.0	97.8 [#] ± 12	97.1 [‡] ± 11.6	96.2 [‡] ± 11.8	97.6 ± 3.00	
	C	97.6 ± 10	99.3 [#] ± 12	98.5 ± 10	99.5 ± 11.2	98.7 ± 2.40	
	Mean	96.9 ± 11	95.2 ± 12	94.5 ± 11	94.2 [*] ± 11.2		
Hip Circumference (cm)	CC	119.5 ⁱ ± 11.0	117.4 ^{‡i} ± 12	116.2 ^{‡i} ± 11	115.4 ^{†‡i} ± 10.4	117.1 ± 2.10	T = 0.001
	WW	118.4 ^d ± 11.7	116.3 ^{†‡i} ± 11	116.5 ^{‡i} ± 13	115.4 ^{†‡i} ± 11.7	116.6 ± 2.10	D = 0.131
	JC	120.0 ± 11	117.8 [‡] ± 8.9	117.7 [‡] ± 9.9	114.8 ^{†‡i} ± 9.3	117.6 ± 2.20	T X D = 0.008
	NS	124.8 ± 14.0	122.6 [‡] ± 15	121.1 [‡] ± 14.4	120.5 [‡] ± 15.2	122.3 ± 2.20	
	C	122.9 ± 9.7	122.5 ± 8.9	122.8 ± 11.0	123.7 ± 9.9	123.0 ± 2.50	
	Mean	121.0 ± 12	119.1 ± 12	118.6 ± 12	117.6 [*] ± 11.9		
Waist/Hip Ratio (cm)	CC	0.79 ^g ± 0.06	0.79 ± 0.07	0.79 ± 0.10	0.79 ± 0.10	0.79 ± 0.01	T = 0.755
	WW	0.82 ± 0.06	0.80 [#] ± 0.07	0.80 [‡] ± 0.10	0.80 [‡] ± 0.10	0.81 ± 0.01	D = 0.815
	JC	0.81 ± 0.06	0.80 ± 0.06	0.80 ± 0.10	0.81 ± 0.10	0.80 ± 0.01	T X D = 0.325
	NS	0.80 ± 0.06	0.80 ± 0.06	0.80 ± 0.10	0.80 ± 0.10	0.80 ± 0.01	
	C	0.80 ± 0.06	0.81 [#] ± 0.07	0.80 ± 0.10	0.80 ± 0.10	0.80 ± 0.01	
	Mean	0.80 ± 0.06	0.80 ± 0.07	0.80 ± 0.10	0.80 ± 0.10		

Values are represented as means±standard deviation except group means are ±standard error mean. n = 133; CC (n=29), WW (n=29), JC (n=27), NS (n=28), and C (n=20). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p<0.05 (univariate). † = significant diet effect p<0.05 (univariate). ‡ = significant time effect from baseline p<0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC (p < 0.05). b = significantly different than WW (p < 0.05). c = significantly different than JC (p < 0.05). d = significantly different than NS (p < 0.05). e = significantly different than C (p < 0.05). # = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). f = a trend toward significance compared to CC (p > 0.05 and p < 0.1). g = a trend toward significance compared to WW (p > 0.05 and p < 0.1). h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). i = a trend toward significance compared to NS (p > 0.05 and p < 0.1). j = a trend toward significance compared to C (p > 0.05 and p < 0.1).

Anthropometric Measurements

Waist and hip measurements as well as waist to hip ratio were assessed by MANOVA at 0, 4, 8, and 12 weeks. There was an overall time (Wilks' Lambda p<0.001) effect and time x diet (Wilks' Lambda p<0.004) effect. As seen in Table 11, post hoc analysis revealed a significant decrease in waist circumference for WW and JC at weeks 4 (WW p<0.001 JC p=0.003), 8 (WW p<0.001 JC p=0.002), and 12 (WW -4.3±6.4, p<0.001; JC -3.7±3.8 cm p=0.001). CC and NS revealed a trend at week 4 (CC p=0.066, NS p=0.060) but were both significant at weeks 8 (CC p=0.001 NS p=0.009) and week 12

(CC -2.8 ± 5.0 , $p=0.008$; NS -3.2 ± 6.2 cm, $p=0.003$). The C group had a trend toward a significant decrease at week 4 ($p=0.096$). By week 12, CC ($p=0.004$), WW ($p<0.001$), and JC ($p=0.001$) and NS ($p=0.002$) had a significantly greater decrease in waist circumference compared to the C group, seen in Figure 13.

When assessing hip circumference, there was a significant decrease from baseline for CC, WW, JC, and NS at weeks 4 (CC $p=0.019$, WW $p=0.027$; JC $p=0.023$; NS $p=0.015$), 8 (CC $p<0.001$ WW $p<0.009$; JC $p=0.003$; NS $p<0.001$), and 12 (CC -4.1 ± 4.9 , $p<0.001$; WW -3.0 ± 2.8 , $p<0.001$; JC -5.1 ± 4.4 , $p<0.001$; NS -4.3 ± 4.2 cm, $p<0.001$). At week 12, CC ($p<0.001$), WW ($p=0.002$), JC ($p<0.001$), and NS ($p<0.001$) also had a

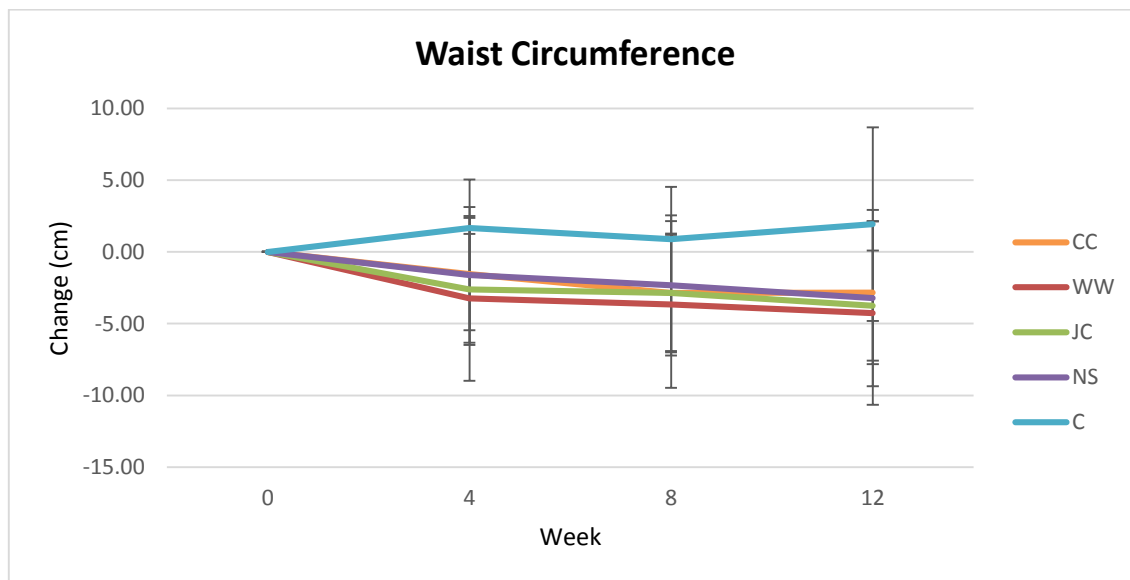


Figure 13: Changes from baseline in waist circumference over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. $n=133$.

significantly greater decrease in hip circumference compared to the C group, shown in Figure 14. JC also had a significantly lower hip circumference compared to WW at week 12 ($p=0.046$). WW had a significant decrease in waist to hip ratio at weeks 8 ($p=0.009$) and 12 ($p=0.048$), and it was lower than C at week 12 ($p=0.035$).

Markers of Health

Resting Heart Rate and Resting Blood Pressure

Resting heart rate and resting blood pressure were also measured and analyzed by MANOVA at 0, 4, 8, and 12 weeks of intervention. There was an overall time (Wilks' Lambda $p<0.001$) effect seen. Table 12 shows how CC showed a trend toward significance at week 4 ($p=0.054$) and had a significant decrease in resting heart rate at weeks 8

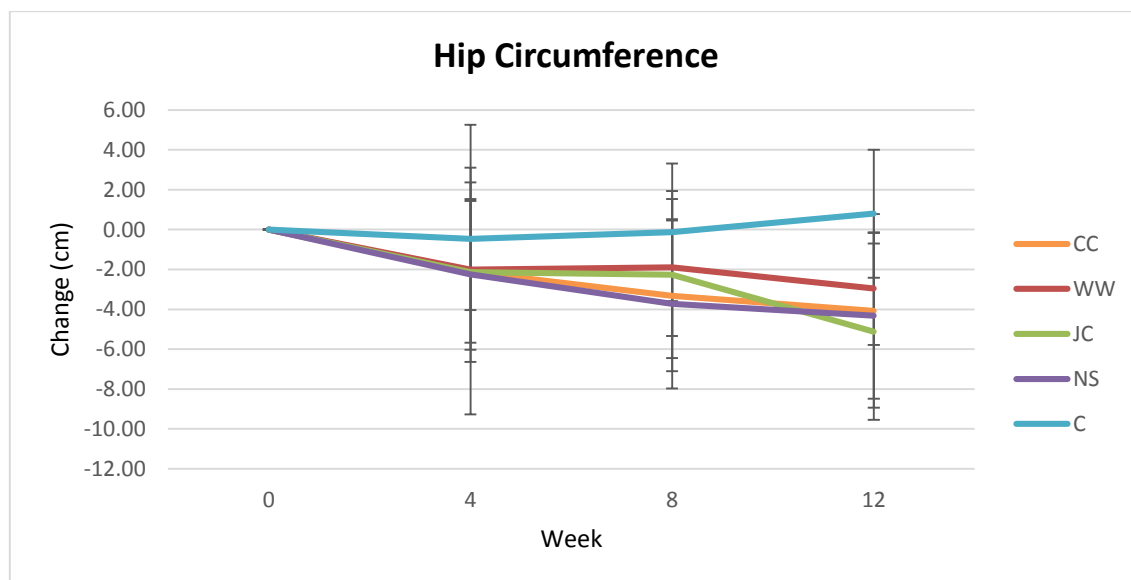


Figure 14: Changes from baseline in hip circumference over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. $n=133$.

Table 12: Changes in resting heart rate and resting blood pressure. Observed between groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C)

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Resting Heart Rate (beats/min)	CC	70.3 ± 9.7	66.8 [#] ± 7.6	63.6 ^{ab} ± 8.6	64.8 ^{ab} ± 9.2	66.3 ± 1.1	T = 0.001
	WW	69.7 ± 6.4	70.5 ^{cd} ± 8.6	67.9 ⁱ ± 8.1	68.8 ^d ± 7.2	69.2 ± 1.0	D = 0.059
	JC	70.4 ± 9.6	64.4 [†] ± 9.2	64.8 [†] ± 7.0	66.6 [†] ± 8.8	66.6 ± 1.1	T x D = 0.308
	NS	67.5 ± 7.6	63.9 [‡] ± 7.2	64.3 ± 8.1	63.7 [‡] ± 6.9	64.9 ± 1.1	
	C	67.4 ± 9.0	68.2 ± 10.7	66.6 ± 7.7	67.3 ± 6.7	67.4 ± 1.3	
	Mean	69.2 ± 8.5	66.7 ± 8.8	65.4 ± 8.0	66.1* ± 8.0		
Resting Systolic (mm/Hg)	CC	127.5 ± 16.2	121.8 [†] ± 9.3	122.3 [†] ± 9.2	119.9 [†] ± 10.8	123 ± 2.0	T = 0.005
	WW	125.6 ± 10.4	122.7 ± 10.8	123.3 ± 11.7	122.9 ± 11.4	124 ± 2.0	D = 0.023
	JC	124.2 ⁱ ± 11	122.2 ± 10.4	123.6 ± 10.7	123.0 ± 10.5	123 ± 2.1	T x D = 0.110
	NS	131.1 ± 19	124.8 [†] ± 17.1	123.4 [†] ± 11.7	122.0 [†] ± 12.8	125 ± 2.0	
	C	130.5 ± 11	133.5 ^{abcd} ± 18.3	133.7 ^{abcd} ± 16.3	132.4 ^{abcd} ± 17.7	132.5 [†] ± 2.5	
	Mean	127.6 ± 14	124.4 ± 13.7	124.7 ± 12.2	123.5* ± 12.9		
Resting Diastolic (mm/Hg)	CC	78.3 ^e ± 6.9	75.2 [‡] ± 6.3	74.3 ^{‡e} ± 6.1	74.7 ^{‡e} ± 7.0	75.6 ± 1.2	T = 0.035
	WW	76.9 ^e ± 8.3	77.2 ± 7.2	77.6 ± 8.4	77.6 ^j ± 8.8	77.3 ± 1.2	D = 0.010
	JC	79.1 ⁱ ± 9.5	77.1 ± 8.3	77.0 ± 10.1	79.3 ± 9.0	78.1 ± 1.2	T x D = 0.766
	NS	80.8 ± 11	78.9 ± 8.2	77.7 [‡] ± 8.1	78.2 ± 7.2	78.9 ± 1.2	
	C	83.8 ± 9.3	83.1 ^{abcd} ± 8.7	80.9 ± 8.9	82.2 ± 10.7	82.5 [†] ± 1.5	
	Mean	79.5 ± 9.1	78.0 ± 8.0	77.3 ± 8.5	78.1* ± 8.7		

Values are represented as means±standard deviation except group means are ±standard error mean. n = 131; CC (n=28), WW (n=29), JC (n=27), NS (n=28), and C (n=19). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p<0.05 (univariate). † = significant diet effect p<0.05 (univariate). ‡ = significant time effect from baseline p<0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC (p < 0.05). b = significantly different than WW (p < 0.05). c = significantly different than JC (p < 0.05). d = significantly different than NS (p < 0.05). e = significantly different than C (p < 0.05). # = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). f = a trend toward significance compared to CC (p > 0.05 and p < 0.1). g = a trend toward significance compared to WW (p > 0.05 and p < 0.1). h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). i = a trend toward significance compared to NS (p > 0.05 and p < 0.1). j = a trend toward significance compared to C (p > 0.05 and p < 0.1).

(p=0.001) and 12 (-5.5±10.0 bpm, p=0.004). JC also had a decrease in resting heart rate at weeks 4 (p=0.002), 8 (p=0.006), and 12 (-3.8±10.9 bpm, p=0.047). NS had a trend toward a significant decrease in heart rate at week 4 (p=0.051) and was significantly lower at week 12 (-3.8±9.1 bpm, p=0.043). Also at week 12, CC expressed a trend toward being significantly lower than WW (p=0.077) and was significantly lower than the C group (p=0.069), shown in Figure 15. Resting systolic blood pressure was also significantly lower for CC and NS at weeks 4 (CC p=0.011; NS p=0.005), 8 (CC p=0.038; NS p=0.002), and 12 (CC -7.6±14.2, p=0.002; NS -9.1±13.7 bpm, p<0.001). At week 12, CC was trending toward significantly lower compared to JC (p=0.067) and was significantly lower

than C ($p=0.014$), depicted in Figure 16. NS showed a trend toward being significantly lower than WW ($p=0.059$) and was significantly lower than JC ($p=0.024$) and the C group ($p=0.004$) at week 12 as well. Depicted in Figure 17, CC experienced a trend toward a decrease in resting diastolic blood pressure at week 4 ($p=0.070$) and had a significant decrease at weeks 8 ($p=0.023$) and 12 ($p=0.045$). NS showed a trend downward at week 8 ($p=0.077$) but was not significant at week 12. CC expressed a trend toward having a significantly greater decrease in diastolic blood pressure compared to WW ($p=0.087$) at week 12. Therefore, we accept H_{o4} since statistically significant differences were observed among groups in variables relating to markers of health.

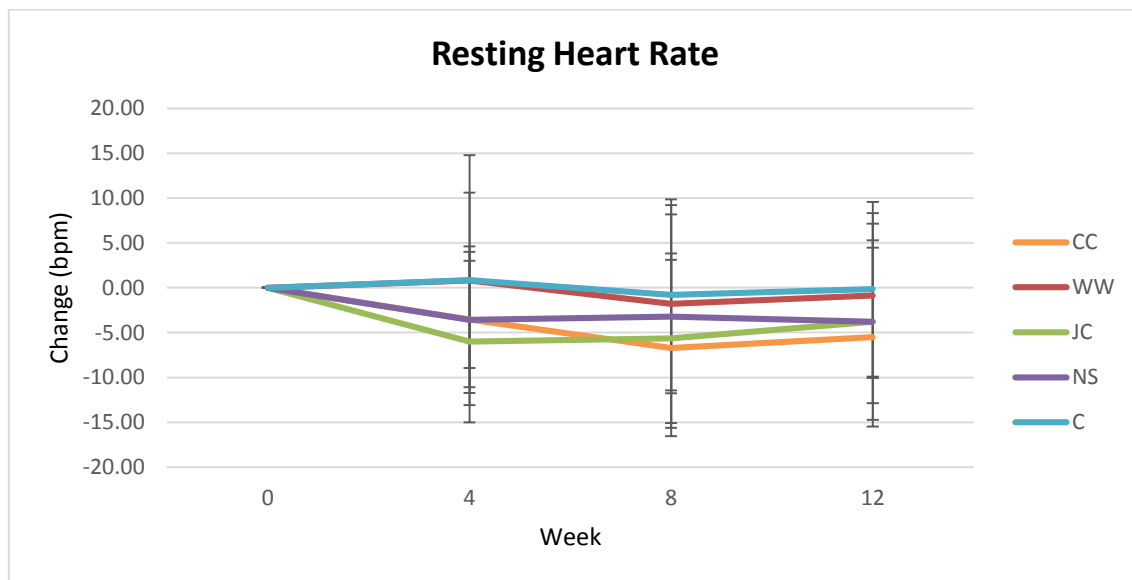


Figure 15: Changes from baseline in resting heart rate over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. $n=131$.

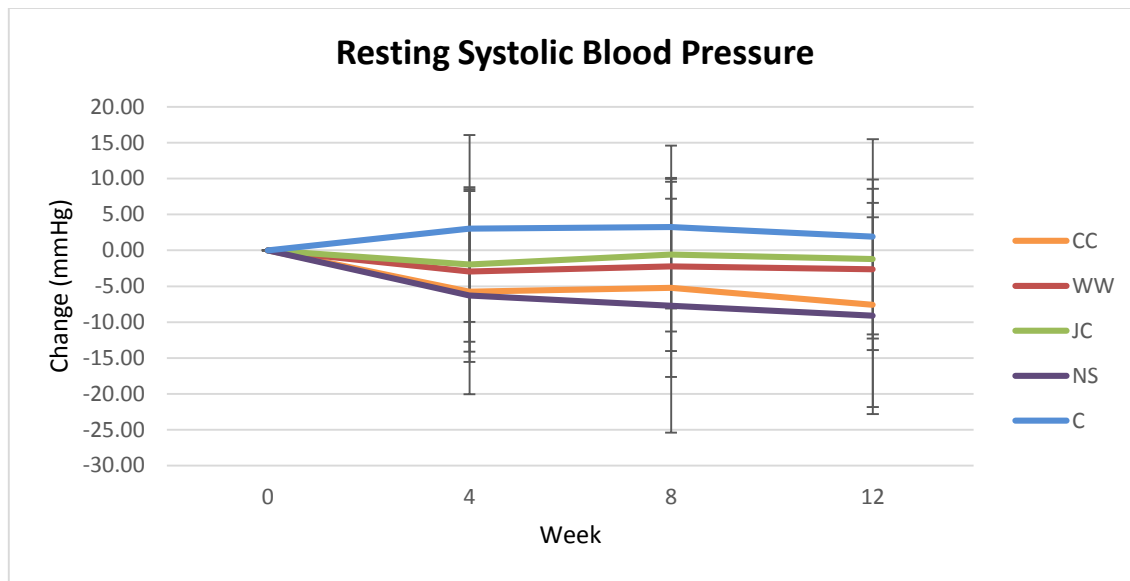


Figure 16: Changes from baseline in resting systolic blood pressure over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. n=131.

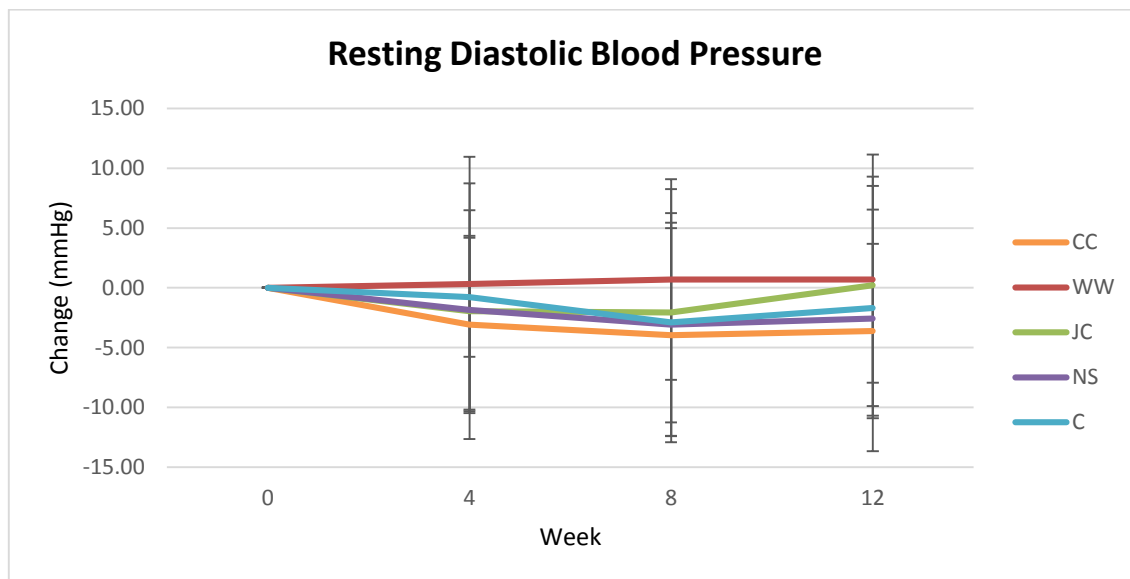


Figure 17: Changes from baseline in resting diastolic blood pressure over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. n=131.

Blood Lipid Panel

A fasting lipid panel was measured at 0, 4, 8, and 12 weeks of the study intervention and analyzed by MANOVA. There was an overall time (Wilks' Lambda $p < 0.001$) effect seen. Changes are expressed as percent change from baseline. Table 13 depicts the changes in lipids through the 12 weeks. JC experienced a significant increase in triglycerides at week 12 with a percent change of $15.1 \pm 42.6\%$, $p = 0.016$. As seen in Figure 18, NS had a trend toward a significant increase as well as weeks 8 ($p = 0.058$) and 12 ($p = 0.064$). Additionally, at week 12 CC ($-6.7 \pm 26.4\%$) had a greater percent decrease in triglycerides compared to JC (15.1 ± 42.6 , $p = 0.012$) and NS (11.1 ± 29.1 , $p = 0.037$), and WW ($-2.7 \pm 31.2\%$) also had a significantly greater decrease compared to JC ($p = 0.038$) as well. When looking at total cholesterol, CC had a significant decrease at week 4 ($p = 0.009$), showed a downward trend at week 8 ($p = 0.078$), but was not significant at week 12 (-3.6 ± 10.0 , $p = 0.119$). WW had a significant decrease at week 4 ($p = 0.010$) as did JC ($p = 0.003$). NS also showed a significant decrease at weeks 4 ($p = 0.033$) and 8 ($p = 0.047$) and a trend at week 12 ($-3.8 \pm 15.5\%$, $p = 0.095$). No significant differences were observed between groups at week 12 in changes in total cholesterol. Percent changes in HDL-cholesterol (HDL-C) were significantly lower in JC at week 4 ($p < 0.001$) and 8 ($p = 0.011$) and expressed a trend downward at week 12 ($-5.0 \pm 16.3\%$, $p = 0.069$), as seen in Figure 19. NS also had a significant decrease in percent change at week 4 ($p = 0.006$) and 8 ($p = 0.008$). Changes in HDL-C were significantly different at week 12 between CC and JC ($p = 0.049$), with CC having the greatest increase of all the groups ($2.5 \pm 15.1\%$). CC also showed a

Table 13: Changes in fasting blood lipids. Observed between groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C)

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Triglycerides (mg/dL)	CC	127.8 ± 64.6	122.9 ± 60.7	118.4 ± 68.2	115.0 ^{hi} ± 58.7	121.0 ± 9.1	T = 0.076
	WW	130.0 ± 60.9	109.5 [†] ± 44.7	118.9 ± 37.7	116.6 ^{hi} ± 44.4	118.8 ± 8.9	D = 0.724
	JC	132.9 ± 60.0	125.8 ± 50.5	133.3 ± 54.9	140.4 ± 57.3	133.1 ± 9.4	T X D = 0.296
	NS	128.0 ± 51.5	126.5 ± 50.8	136.9 ± 64.4	134.3 ± 45.6	131.5 ± 9.1	
	C	140.0 ± 58.4	128.0 ± 43.2	122.4 [#] ± 40.2	133.3 ± 44.0	130.9 ± 11	
	Mean	131.1 ± 58.5	122.0 ± 50.4	126.0 ± 54.8	137.3 ± 50.9		
Total Cholesterol (mg/dL)	CC	191.4 ± 30.8	178.8 [†] ± 28.0	183.1 [#] ± 32.9	184.2 [#] ± 33.0	184.4 ± 5.5	T = 0.001
	WW	187.5 ± 35.5	174.5 ^{ab} ± 28.4	180.6 ± 31.6	186.9 ± 33.0	182.4 ± 5.4	D = 0.802
	JC	189.1 ± 29.3	174.2 ^{ab} ± 29.0	181.2 [#] ± 27.6	183.7 ± 28.0	182.1 ± 5.7	T X D = 0.316
	NS	189.7 ± 39.9	177.7 ^{hi} ± 31.3	178.5 [†] ± 29.8	179.0 [†] ± 29.2	181.2 ± 5.5	
	C	192.9 ± 33.1	192.4 ^{bd} ± 32.5	190.6 ± 31.9	188.2 ± 35.6	191.0 ± 6.5	
	Mean	190.0 ± 33.6	178.8 ± 29.9	182.3 ± 30.6	184.2* ± 31.4		
HDL-C (mg/dL)	CC	54.8 ± 13.2	52.4 ^{hch} ± 11.5	54.8 ^{gh} ± 15.6	55.8 ^{ghj} ± 14.3	54.4 ± 2.1	T = 0.001
	WW	54.1 ± 13.3	50.9 [†] ± 12.0	51.4 [†] ± 11.6	53.9 ⁱ ± 14.1	52.6 ± 2.1	D = 0.266
	JC	53.5 ± 12.3	46.8 [†] ± 7.7	49.1 [†] ± 8.4	49.7 [†] ± 7.8	49.8 ± 2.2	T X D = 0.009
	NS	51.0 ± 14.0	46.7 [†] ± 9.9	46.8 [†] ± 10.6	48.2 [†] ± 11.6	48.2 ± 2.1	
	C	51.4 ± 10.5	51.8 ± 11.9	49.6 ± 10.5	49.2 ± 12.2	50.5 ± 2.5	
	Mean	53.1 ± 12.7	49.6 ± 10.8	50.4 ± 11.9	51.5* ± 12.5		
LDL-C (mg/dL)	CC	111.1 ± 22.7	101.7 ^{hi} ± 21.8	103.1 ^{hi} ± 25.2	105.4 ± 22.7	105.3 ± 4.8	T = 0.001
	WW	107.3 ± 31.8	101.8 ^j ± 24.7	105.5 ± 29.1	109.3 ± 27.7	106.0 ± 4.7	D = 0.555
	JC	108.9 ± 25.4	100.8 ^{hi} ± 26.4	105.4 ± 24.8	106.0 ± 27.0	105.3 ± 5.0	T X D = 0.597
	NS	113.0 ± 32.1	105.6 [#] ± 26.2	104.4 [†] ± 21.9	104.0 [†] ± 28.1	106.8 ± 4.8	
	C	122.3 ± 50.7	115.0 ± 32.6	116.6 ± 26.6	112.4 [†] ± 30.7	116.6 ± 5.7	
	Mean	112.0 ± 32.6	104.4 ± 26.2	106.4 ± 25.6	107.1* ± 26.9		
TC/HDL-C	CC	3.65 ± 0.85	3.55 ⁱ ± 0.88	3.53 ^{ij} ± 0.97	3.45 ^{hi} ± 0.78	3.54 ± 0.16	T = 0.336
	WW	3.62 ± 0.90	3.56 ⁱ ± 0.80	3.66 ± 0.86	3.59 ± 0.80	3.61 ± 0.16	D = 0.380
	JC	3.64 ± 0.73	3.78 ± 0.73	3.77 ± 0.78	3.77 ± 0.79	3.74 ± 0.17	T X D = 0.734
	NS	3.90 ± 0.92	3.95 ± 0.91	3.96 ± 0.88	3.87 ± 0.92	3.92 ± 0.16	
	C	3.90 ± 1.00	3.88 ± 1.05	4.00 ± 1.04	3.82 ± 1.46	3.90 ± 0.19	
	Mean	3.73 ± 0.88	3.73 ± 0.88	3.77 ± 0.91	3.69 ± 0.95		

Values are represented as means±standard deviation except group means are ±standard error mean. n = 131; CC (n=28), WW (n=29), JC (n=26), NS (n=28), and C (n=20). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p<0.05 (univariate). † = significant diet effect p<0.05 (univariate). ‡ = significant time effect from baseline p<0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC (p < 0.05). b = significantly different than WW (p < 0.05). c = significantly different than JC (p < 0.05). d = significantly different than NS (p < 0.05). e = significantly different than C (p < 0.05). # = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). f = a trend toward significance compared to CC (p > 0.05 and p < 0.1). g = a trend toward significance compared to WW (p > 0.05 and p < 0.1). h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). i = a trend toward significance compared to NS (p > 0.05 and p < 0.1). j = a trend toward significance compared to C (p > 0.05 and p < 0.1).

trend toward significance when compared to NS (p=0.082) and the C group (p=0.068).

LDL-cholesterol (LDL-C) percent changes were significantly lower in CC at week 4 (p=0.029) and expressed a trend at week 8 (p=0.062). Though the changes were not

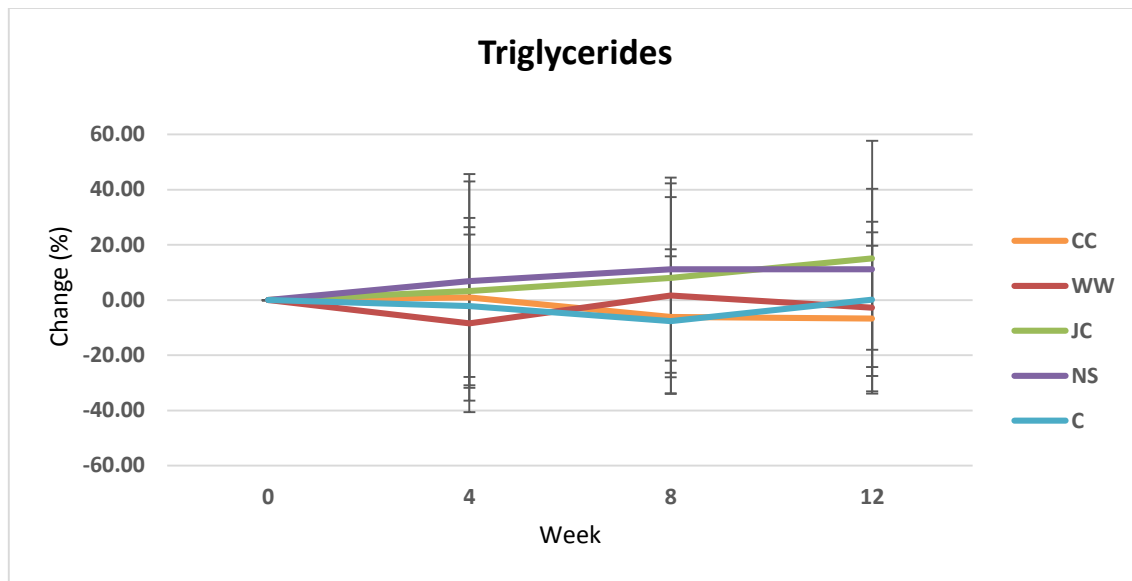


Figure 18: Changes from baseline in triglycerides over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are percent change means \pm SD. n=131.

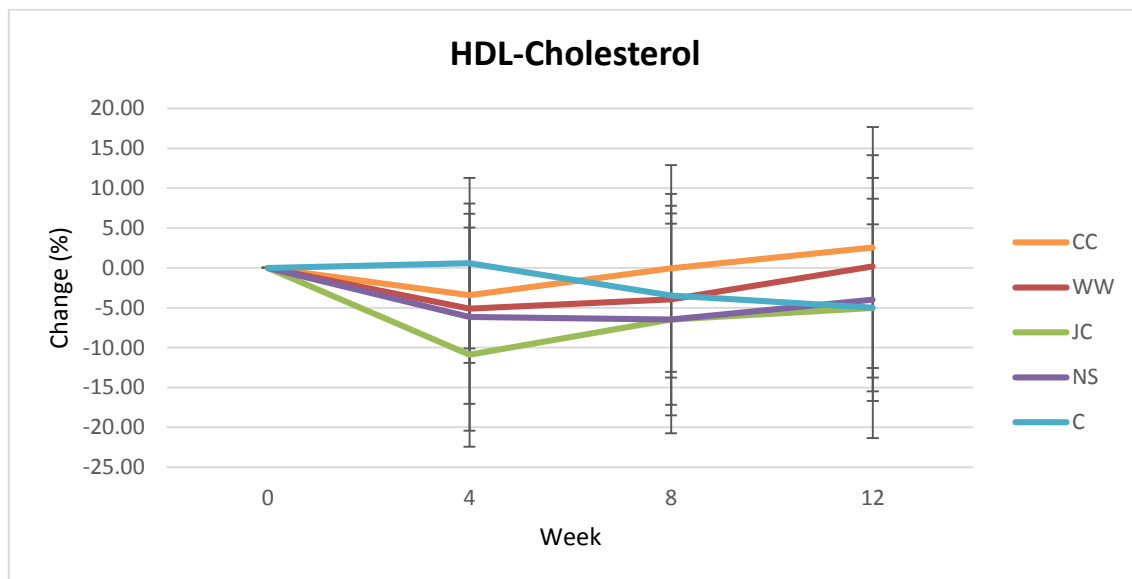


Figure 19: Changes from baseline in HDL-cholesterol over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are percent change means \pm SD. n=131.

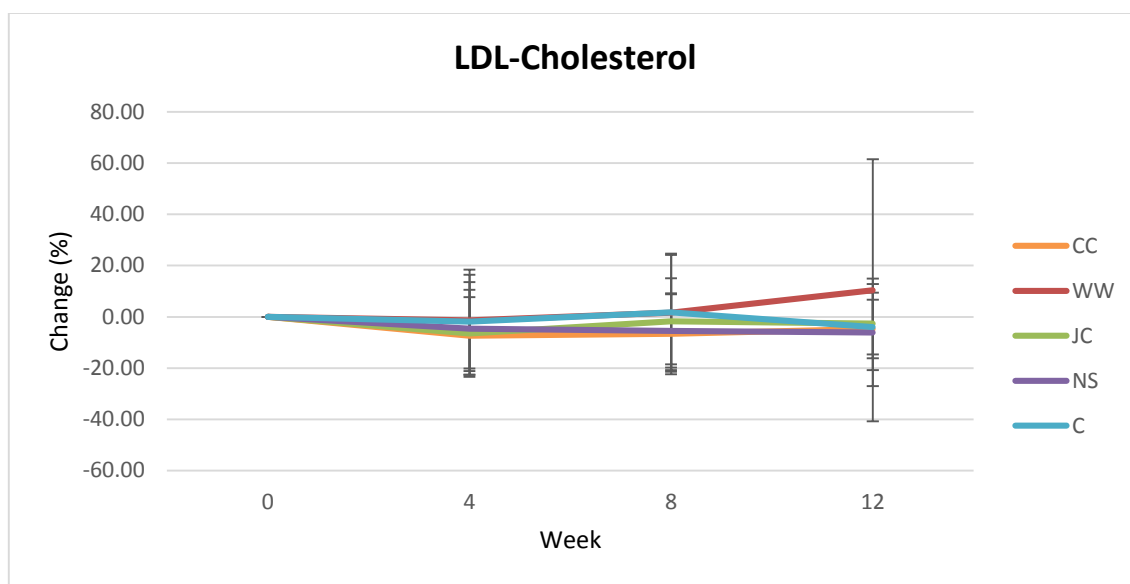


Figure 20: Changes from baseline in LDL-cholesterol over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are percent change means \pm SD. n=131.

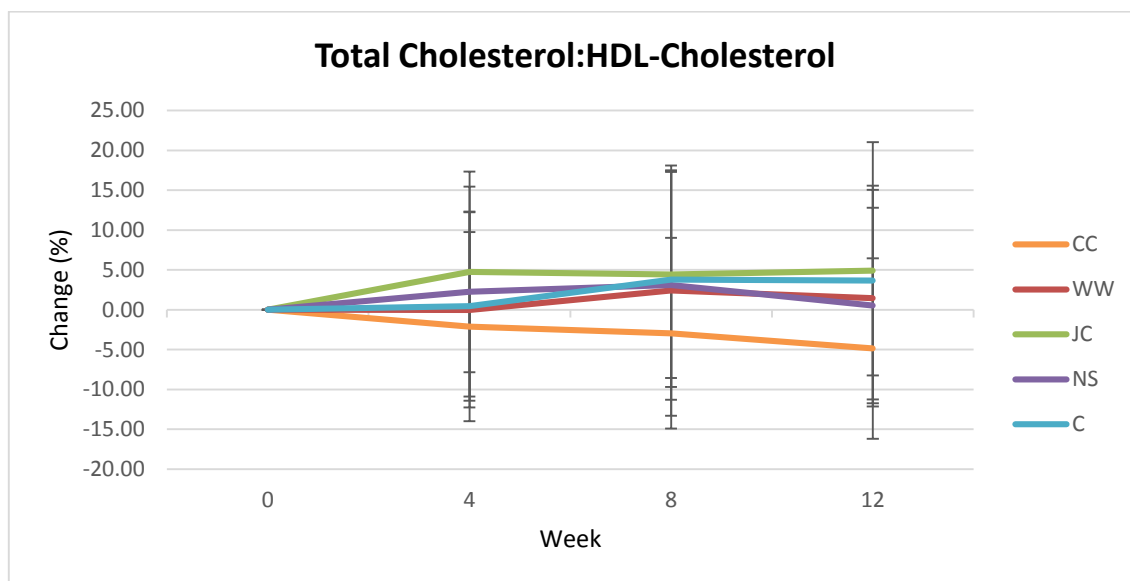


Figure 21: Changes from baseline in total cholesterol:HDL-cholesterol over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are percent change means \pm SD. n=131.

significant at week 12 for the CC group ($-4.7 \pm 11.5\%$, $p=0.370$). WW however, had an increase in LDL-C percent change from baseline at week 12 ($10.3 \pm 51.2\%$, $p=0.047$). CC ($p=0.043$) and NS ($p=0.028$) had significantly greater decreases in LDL-C compared to WW, with NS having the greatest decrease ($-6.1 \pm 21.0\%$, $p=0.250$), shown in Figure 20. When assessing total cholesterol to HDL-C ratio, CC showed a trend toward a significant decrease ($-4.9 \pm 11.3\%$, $p=0.053$) at week 12. Whereas, JC showed a trend toward a significant increase ($4.9 \pm 16.1\%$, $p=0.061$) at week 12. Figure 21 depicts how the ratio of total cholesterol to HDL-C significantly decreased in CC compared to JC ($p=0.007$) and the C group ($3.7 \pm 11.9\%$, $p=0.029$) and expressed a trend when compared to WW ($1.5 \pm 13.6\%$, $p=0.072$). Therefore, due to the changes seen in the lipid levels, we accept Ho6 since statistically significant differences were observed among groups in blood lipid panels.

Hormone Levels

Glucose, insulin, glucose/insulin ratio, and calculated HOMA were analyzed at weeks 0, 4, 8, and 12 by MANOVA. There was an overall time (Wilks' Lambda $p=0.016$) but no time x diet (Wilks' Lambda $p=0.121$) effect. Change from baseline is presented as percent change. When looking at percent change from baseline in glucose levels, no significant changes were seen in any of the groups at any time point ($p=0.132$), depicted in Table 14. Additionally, there was not a significant group effect ($p=0.642$). Though not significant, CC had the greatest decrease in glucose at week 12 ($-3.8 \pm 14.9\%$, $p=0.240$). When analyzing insulin levels, Figure 22 shows that NS was the only group that had a

Table 14: Changes in hormones. Observed between groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C)

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Glucose (mg/dL)	CC	98.6 ± 23.5	94.7 ± 15.5	99.4 ± 19	92.3 [#] ± 12	96.3 ± 3.2	T = 0.040
	WW	93.3 ± 12.9	92.2 ± 8.4	92.1 ± 10.9	90.8 ⁱ ± 9.8	92.1 ± 2.6	D = 0.516
	JC	97.8 ± 11.6	92.8 [‡] ± 7.6	94.7 ± 10.1	96.4 ± 13.2	95.4 ± 2.3	T x D = 0.403
	NS	100.9 ± 12.3	95.5 [‡] ± 8.9	98.6 ± 9.0	98.4 ± 9.8	98.3 ± 2.6	
	C	96.2 ± 10.9	97.9 ± 12.5	99.0 ± 7.9	96.1 ± 10.9	97.3 ± 2.8	
	Mean	97.4 ± 13.9	94.4 ± 10.2	96.4 ± 11.3	95.1 ± 11.3		
Insulin (μU/ml)	CC	13.7 ± 9.0	9.3 [#] ± 4.6	8.6 [#] ± 4.9	8.9 [#] ± 5.9	10.1 ± 2.6	T = 0.064
	WW	14.4 ± 7.2	14.2 ± 12.9	16.8 ^h ± 19.6	11.7 ± 11.5	14.3 ± 2.1	D = 0.600
	JC	13.0 ± 6.2	11.0 ± 7.6	9.6 ± 5.0	9.7 ^{hi} ± 4.8	10.8 ± 1.8	T x D = 0.288
	NS	15.7 ± 12.5	13.2 ± 14.5	12.7 ± 9.8	13.8 ± 7.2	13.8 ± 2.1	
	C	11.5 ± 8.4	12.8 ± 6.7	14.1 ± 9.9	11.5 ± 4.9	12.5 ± 2.3	
	Mean	13.7 ± 8.7	12.2 ± 10.1	12.4 ± 11.3	11.2 ± 7.3		
Glucose/Insulin Ratio	CC	10.8 ± 7.1	14.3 ± 11.1	16.4 [#] ± 10.4	15.9 [#] ± 12.9	14.3 ± 2.6	T = 0.302
	WW	9.0 ± 6.8	11.6 ± 8.0	13.8 [#] ± 17.2	12.9 [#] ± 8.8	11.8 ± 2.1	D = 0.895
	JC	9.1 ± 4.4	17.5 [‡] ± 22.6	12.9 ± 7.3	13.4 [‡] ± 8.9	13.2 ± 1.9	T x D = 0.219
	NS	12.3 ± 11.9	13.5 ± 9.1	12.0 ± 8.4	9.7 ± 6.4	11.9 ± 2.1	
	C	13.5 ± 11.6	9.8 ± 5.3	9.6 ± 4.6	12.4 ± 11.7	11.3 ± 2.3	
	Mean	10.8 ± 8.6	13.6 ± 13.7	12.8 ± 10.3	12.6 ± 9.5		
HOMA^k	CC	3.68 ± 3.24	2.29 [‡] ± 1.40	2.21 [‡] ± 1.54	2.10 ^{‡i} ± 1.53	2.57 ± 0.64	T = 0.007
	WW	3.42 ± 2.01	3.24 ± 2.77	3.84 ^h ± 4.18	2.62 ± 2.42	3.28 ± 0.53	D = 0.719
	JC	3.23 ± 1.85	2.57 ± 1.90	2.26 [#] ± 1.30	2.35 ^{hi} ± 1.46	2.60 ± 0.46	T x D = 0.170
	NS	4.02 ± 3.45	3.12 [#] ± 3.41	3.15 ± 2.63	3.31 ± 1.61	3.40 ± 0.51	
	C	2.70 ± 2.00	3.02 ± 1.45	3.47 ± 2.62	2.70 ± 1.12	2.97 ± 0.57	
	Mean	3.41 ± 2.50	2.87 ± 2.35	2.98 ± 2.66	2.64 ± 1.69		
Leptin (ng/ml)	CC	53.9 ± 19.1	38.4 [‡] ± 15.8	34.7 ^{‡e} ± 12.0	37.3 ^{‡e} ± 19.0	41.1 ± 6.7	T = 0.238
	WW	52.7 ± 30.2	38.0 [‡] ± 21.1	41.2 ^{‡i} ± 26.0	41.0 ^{‡i} ± 22.9	43.2 ± 5.6	D = 0.009
	JC	52.8 ± 24.3	36.5 [‡] ± 25.2	42.9 [‡] ± 33.5	43.5 ^{‡j} ± 32.0	43.9 ± 5.2	T x D = 0.001
	NS	52.8 ± 23.6	42.6 [‡] ± 25.8	44.0 ± 27.7	49.0 ± 33.1	47.1 ± 5.8	
	C	55.9 ± 18.7	64.8 ^{abod} ± 22.8	58.5 ± 26.3	60.4 ± 39.0	59.9 [‡] ± 6.4	
	Mean	53.5 ± 23.5	43.1 ± 24.4	44.1 ± 27.3	46.0 ± 28.5		

Values are represented as means±standard deviation except group means are ±standard error mean. n = 74, except leptin n = 78; CC (n=22), WW (n=27), JC (n=24), NS (n=25), and C (n=19). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p<0.05 (univariate). † = significant diet effect p<0.05 (univariate). ‡ = significant time effect from baseline p<0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC (p < 0.05). b = significantly different than WW (p < 0.05). c = significantly different than JC (p < 0.05). d = significantly different than NS (p < 0.05). e = significantly different than C (p < 0.05). # = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). f = a trend toward significance compared to CC (p > 0.05 and p < 0.1). g = a trend toward significance compared to WW (p > 0.05 and p < 0.1). h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). i = a trend toward significance compared to NS (p > 0.05 and p < 0.1). j = a trend toward significance compared to C (p > 0.05 and p < 0.1). k = Homeostatic Model Assessment.

significant increase (32.4±106.4, p=0.045) at week 12, though C had a significant increase at week 4 (p=0.015) and 8 (p=0.019). At week 12, CC (-28.1±31.1, p=0.021), WW (-

19.2±50.9, $p=0.027$), and JC (-19.0±38.4%, $p=0.018$) had a greater change in insulin levels when compared to NS. CC ($p=0.073$) and JC ($p=0.084$) also had a trend toward a significant change compared to the C group at week 12. CC showed a significant increase in glucose to insulin ratio at week 8 ($p=0.004$) and 12 (57.8±72.9%, $p=0.012$), seen in Figure 23. WW and JC also did at week 4 (WW $p=0.024$; JC $p=0.003$), week 8 (WW $p=0.014$; JC $p=0.005$), and week 12 (WW 53.1±61.6, $p=0.005$; JC 52.7±80.2%, $p=0.001$). NS expressed a trend toward a significant increase at week 4 ($p=0.087$), a significant increase at week 8 ($p=0.036$), but the change at week 12 was not significant (13.7±69.1%, $p=0.441$). There was not a significant MANOVA univariate interaction ($p=0.456$), though CC ($p=0.073$), WW ($p=0.069$), and JC ($p=0.055$) expressed trends toward a significant increase compared to C at week 12. No significant changes from baseline were observed in calculated HOMA at week 12, when presented as percent change from baseline, in any of the diet groups, seen in Figure 24. Though, the C group had a significant increase at week 4 ($p=0.012$) and 8 ($p=0.030$). A significant interaction was also seen when analyzed by MANOVA univariate ($p=0.031$). CC (-31.1±32.6, $p=0.020$), WW (-21.4±48.3, $p=0.028$), and JC (-17.7±45.1%, $p=0.028$) had a significant decrease in HOMA levels when compared to NS (30.7±106.4%) at week 12. Trends were also seen in CC ($p=0.059$), WW ($p=0.087$), and JC ($p=0.096$) when compared to the C group at week 12.

Leptin was also assessed at weeks 0, 4, 8, and 12 by ANOVA. An overall time (Wilks' Lambda $p=0.001$) and time x diet (Wilks' Lambda $p=0.047$) effect was seen. Figure 25 shows no significant changes in leptin levels were observed at week 12, though CC expressed trends toward a significant decrease at week 4 ($p=0.061$) and 8 ($p=0.076$)

and had the greatest decrease of all the groups at week 12 ($-21.1 \pm 21.4\%$, $p=0.151$). WW had a significant decrease at week 4 ($p=0.007$) and a trend downward at week 8 ($p=0.089$). JC also had significant decreases at week 4 ($p<0.001$) and 8 ($p=0.030$). NS and C both had a significant increase at week 4 (NS $p=0.030$; C $p=0.046$). Due to changes seen in hormone levels, we are therefore able to accept Ho7 since statistically significant differences were observed among groups in hormone levels.

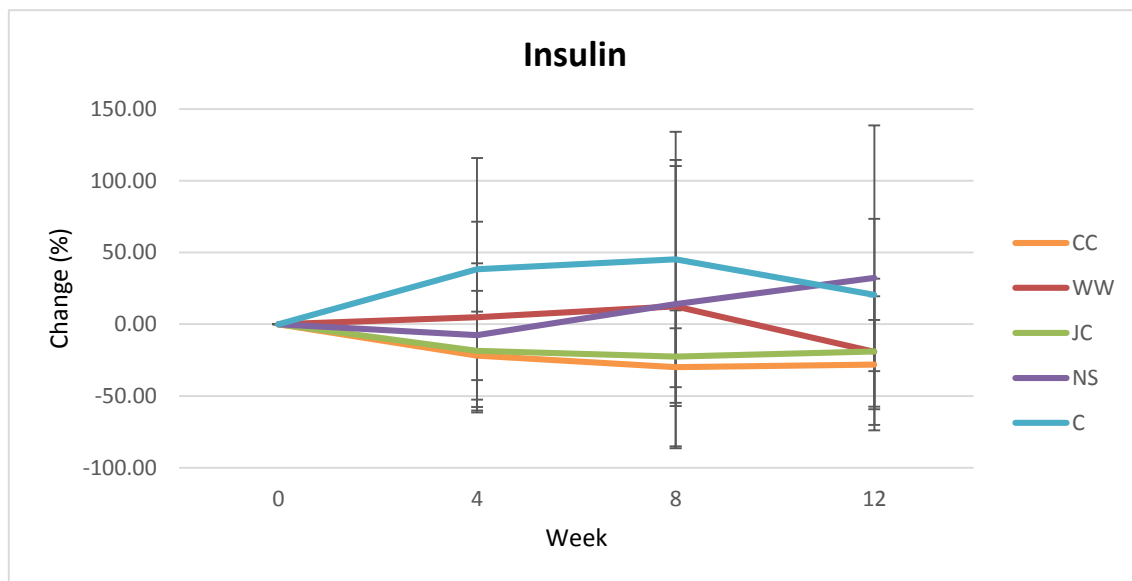


Figure 22: Changes from baseline in insulin levels over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are percent change means \pm SD. $n=74$.

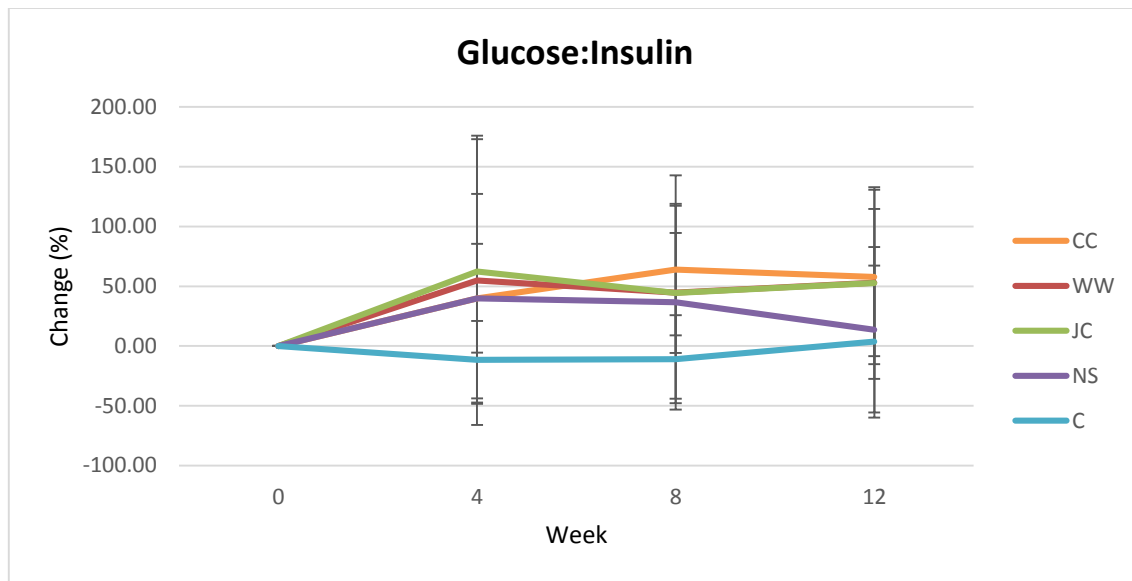


Figure 23: Changes from baseline in glucose to insulin ratio over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are percent change means \pm standard deviation. n=74.

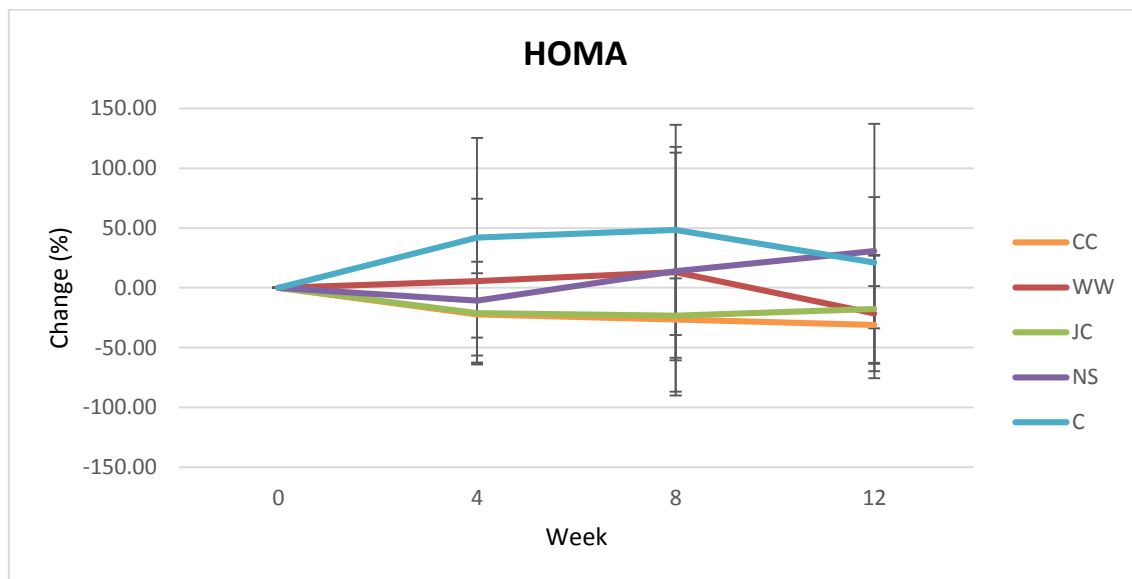


Figure 24: Changes from baseline in calculated HOMA levels over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are percent change means \pm SD. n=74.

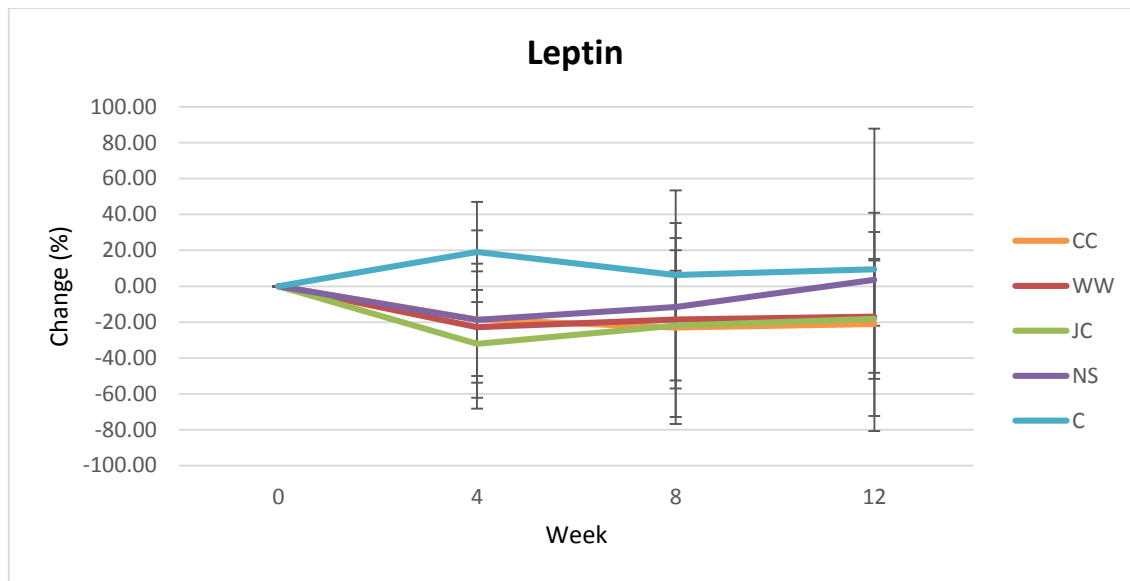


Figure 25: Changes from baseline in leptin levels over 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are percent change means \pm SD. n=78.

Markers of Fitness

Peak Aerobic Capacity

Peak aerobic capacity was measured at baseline and 12 weeks by ANOVA and represented as liters per minute, milliliters per kilogram per minute, and maximum time to exhaustion. When represented as L/min, there was an overall time x diet (Wilks' Lambda $p < 0.007$) effect. As depicted in Table 15, CC (0.11 ± 0.17 , $p = 0.001$) and WW (0.06 ± 0.22 , $p = 0.050$) had an increase in absolute peak aerobic capacity. CC also had a greater absolute peak aerobic capacity at week 12 compared to JC ($p = 0.022$), NS ($p = 0.002$), and C ($p = 0.004$). WW had a greater increase compared to NS ($p = 0.032$) and C ($p = 0.004$) as well.

Table 15: Changes in peak aerobic capacity. Observed between groups at 0 and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C).

Variable	Group	Baseline	12 Weeks	Group (SEM)	P-level
VO2 max (L/min)	CC	1.8 ± 0.23	1.94 ^{†e} ± 0.2	1.9 ± 0.06	T = 0.218
	WW	1.8 ± 0.37	1.84 [‡] ± 0.4	1.8 ± 0.06	D = 0.672
	JC	1.8 ± 0.40	1.83 ± 0.3	1.8 ± 0.07	T X D = 0.007
	NS	1.9 ± 0.42	1.84 ± 0.4	1.9 ± 0.06	
	C	1.8 ± 0.30	1.72 ± 0.3	1.7 ± 0.08	
	Mean	1.8 ± 0.35	1.85 ± 0.4		
VO2 max (ml/kg/min)	CC	20.5 ± 3.2	23.0 ^{†de} ± 3.4	22 ± 0.7	T = 0.001
	WW	20.3 ± 4.6	21.4 ^{†e} ± 4.4	21 ± 0.7	D = 0.076
	JC	20.4 ± 3.8	21.8 ^{†e} ± 3.1	21 ± 0.8	T X D = 0.015
	NS	19.8 ± 5.1	20.6 ^j ± 5.7	20 ± 0.7	
	C	18.7 ± 3.1	18.2 ± 3.3	19 ± 0.9	
	Mean	20.0 ± 4.1	21.2* ± 4.4		
Time to Exhaustion (min)	CC	7.6 ^e ± 0.9	8.4 ^{†deg} ± 0.8	8.0 ± 0.2	T = 0.001
	WW	7.2 ± 1.3	7.8 ^{†e} ± 1.3	7.5 ± 0.2	D = 0.024
	JC	7.2 ± 1.2	7.9 ^{†e} ± 1.2	7.6 ± 0.2	T X D = 0.020
	NS	7.2 ± 1.7	7.6 ^j ± 1.7	7.4 ± 0.2	
	C	6.7 ± 1.4	6.8 ± 1.4	6.7 [†] ± 0.3	
	Mean	7.2 ± 1.3	7.8* ± 1.4		
Values are represented as means±standard deviation except group means are ±standard error mean. n = 128; CC (n=28), WW (n=28), JC (n=26), NS (n=28), and C (n=18). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p<0.05 (univariate). † = significant diet effect p<0.05 (univariate). ‡ = significant time effect from baseline p<0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC (p < 0.05). b = significantly different than WW (p < 0.05). c = significantly different than JC (p < 0.05). d = significantly different than NS (p < 0.05). e = significantly different than C (p < 0.05). # = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). f = a trend toward significance compared to CC (p > 0.05 and p < 0.1). g = a trend toward significance compared to WW (p > 0.05 and p < 0.1). h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). i = a trend toward significance compared to NS (p > 0.05 and p < 0.1). j = a trend toward significance compared to C (p > 0.05 and p < 0.1).					

There was also an overall time (Wilks' Lambda p<0.001) and time x diet (Wilks' Lambda p<0.015) effect for peak aerobic capacity when relative to body weight. Figure 26 shows that CC (2.5±2.9, p<0.001), WW (1.1±4.7, p=0.044), and JC (1.4±2.1, p=0.017) all had an increase at week 12 compared to baseline. CC expressed a trend toward significance when compared to WW (p=0.068) and had a significantly greater increase

compared to NS ($p=0.024$) and C ($p=0.001$). There was also a trend toward a significant increase when comparing WW to the C group ($p=0.068$), and JC had a greater increase in relative peak aerobic capacity compared to the C group ($p=0.037$) as well.

When analyzing maximum time to exhaustion, there was a time (Wilks' Lambda $p<0.001$) and time x diet (Wilks' Lambda $p<0.020$) effect. CC ($p<0.001$), WW ($p<0.001$), JC ($p<0.001$), and NS ($p=0.005$) had an increase in time to exhaustion seen at week 12. CC (0.8 ± 0.8) had a greater increase in time to exhaustion compared to NS (0.4 ± 0.5 min, $p=0.032$) and C (0.1 ± 0.6 min, $p=0.003$) at week 12. WW (0.6 ± 0.8 min, $p=0.049$) and JC (0.7 ± 0.9 min, $p=0.010$) also had greater increase in time to exhaustion compared to the C group at week 12.

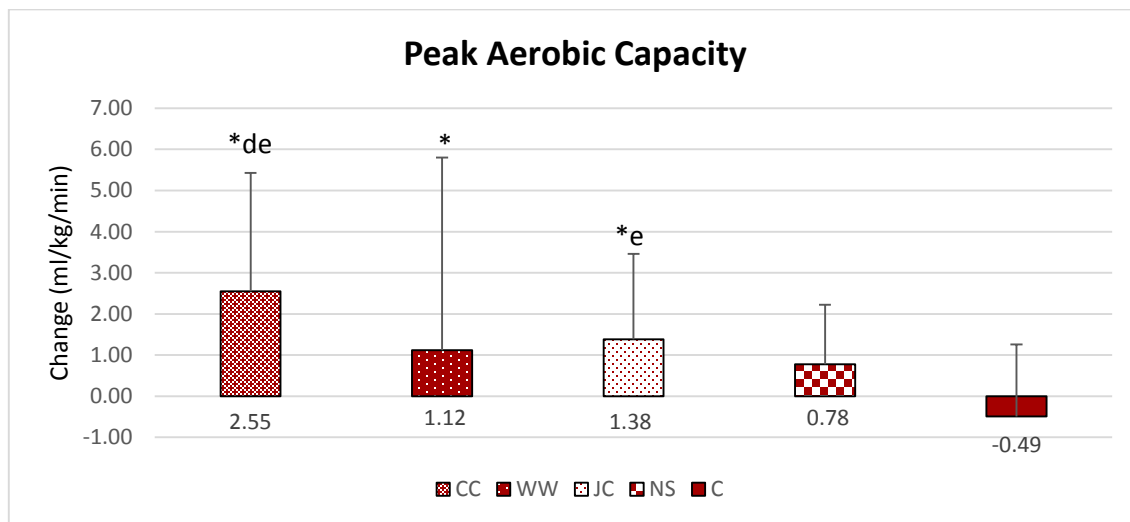


Figure 26: Changes from baseline in peak aerobic capacity after 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. $n=128$. When analyzed by Tukey's LSD post hoc: * significantly different from baseline ($p<0.05$), ^d significantly different than NS ($p<0.05$), ^e significantly different than C ($p<0.05$).

Isotonic Strength and Endurance

Isotonic lower and upper body strength and endurance were measured at baseline and after 12 weeks of diet and exercise intervention. Muscular strength was analyzed by MANOVA, and muscular endurance was analyzed by MANOVA as well. For isotonic lower and upper body strength assessment, there was an overall time (Wilks' Lambda $p=0.015$) and time by diet (Wilks' Lambda $p=0.003$) effect. Changes in lower and upper body strength are expressed as percent change from baseline. As denoted in Table 16, CC ($15.0\pm21.9\%$, $p=0.001$) and C ($13.8\pm22.7\%$, $p=0.010$) had an increase in one repetition maximum (1RM) for isotonic lower body strength seen at week 12. CC showed a trend toward significance compared to WW ($p=0.064$) and NS ($p=0.068$) and experienced a significantly greater increase compared to JC ($p=0.044$) at week 12, seen in Figure 27. For upper body strength test, CC (8.7 ± 12.5 , $p=0.001$) had a significant increase at week 12. WW (4.9 ± 14.8 , $p=0.065$) and JC ($5.4\pm14.0\%$, $p=0.063$) showed a trend toward a significant increase. CC had a greater increase when compared to NS ($p=0.005$) and C ($p=0.023$). NS additionally had a significant decrease in upper body 1RM compared to WW ($p=0.026$) and JC ($p=0.024$), shown in Figure 28.

There was not a significant time (Wilks' Lambda $p=0.390$) or time x diet (Wilks' Lambda $p=0.591$) effect for muscular endurance. CC was the only group that had a significant increase in lower body muscular endurance ($22.8\pm75.1\%$, $p=0.040$) at week 12. Due to changes in peak aerobic capacity, as well as lower and upper body strength and endurance, we can accept H_0 since statistically significant differences were observed among groups in variables relating to markers of fitness.

Table 16: Changes in lower and upper body strength and endurance. Observed between groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C).

Variable	Group	Baseline	12 Weeks	Group (SEM)	P-level
Leg Press 1RM (kg)	CC	169.7 ^d ± 51.6	192.9 [‡] ± 67.8	181.3 ± 10.9	T = 0.007
	WW	169.8 ^d ± 43.0	174.9 ⁱ ± 50.6	172.4 ± 10.7	D = 0.259
	JC	182.2 ± 66.8	179.3 ± 61.9	180.7 ± 11.8	T X D = 0.091
	NS	204.7 ± 63.2	207.7 ± 63.6	206.2 ± 11.1	
	C	178.5 ± 66.1	198.9 [‡] ± 77.9	188.7 ± 13.6	
	Mean	180.9 ± 58.4	190.2* ± 64.0		
Bench Press 1RM (kg)	CC	31.1 ± 6.1	33.5 [‡] ± 6.3	32.3 ± 1.5	T = 0.069
	WW	31.5 ± 7.5	32.9 [#] ± 8.5	32.2 ± 1.4	D = 0.966
	JC	30.6 ± 8.6	32.0 [#] ± 8.6	31.3 ± 1.6	T X D = 0.004
	NS	33.6 ± 8.1	32.2 [#] ± 8.4	32.9 ± 1.5	
	C	32.1 ± 8.9	31.6 ± 9.4	31.8 ± 1.8	
	Mean	31.8 ± 7.7	32.5 ± 8.1		
Leg Press Endurance	CC	14.1 ± 7.5	15.5 ^b ± 9.7	14.8 ± 1.2	T = 0.530
	WW	12.6 ± 5.0	10.5 ^d ± 3.7	11.5 ± 1.4	D = 0.306
	JC	14.8 ± 8.5	14.1 ± 9.3	14.5 ± 1.4	T X D = 0.322
	NS	14.3 ± 5.3	15.3 ± 9.3	14.8 ± 1.3	
	C	13.5 ± 4.6	11.9 ± 2.8	12.7 ± 1.5	
	Mean	13.9 ± 6.4	13.6 ± 8.0		
Bench Press Endurance	CC	8.4 ^j ± 3.5	7.8 ± 3.9	8.1 ± 0.6	T = 0.220
	WW	8.0 ± 2.8	8.0 ^j ± 2.6	8.3 ± 0.6	D = 0.218
	JC	8.4 ^j ± 2.7	7.8 ± 3.3	8.1 ± 0.6	T X D = 0.753
	NS	8.3 ^j ± 5.7	7.0 ± 2.3	7.6 ± 0.6	
	C	6.2 ± 3.4	6.3 ± 2.1	6.3 ± 0.7	
	Mean	7.9 ± 3.9	7.4 ± 3.0		
Values are represented as means±standard deviation except group means are ±standard error mean. n = 126; CC (n=28), WW (n=29), JC (n=24), NS (n=27), and C (n=18). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p<0.05 (univariate). † = significant diet effect p<0.05 (univariate). ‡ = significant time effect from baseline p<0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC (p < 0.05). b = significantly different than WW (p < 0.05). c = significantly different than JC (p < 0.05). d = significantly different than NS (p < 0.05). e = significantly different than C (p < 0.05). # = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). f = a trend toward significance compared to CC (p > 0.05 and p < 0.1). g = a trend toward significance compared to WW (p > 0.05 and p < 0.1). h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). i = a trend toward significance compared to NS (p > 0.05 and p < 0.1). j = a trend toward significance compared to C (p > 0.05 and p < 0.1).					

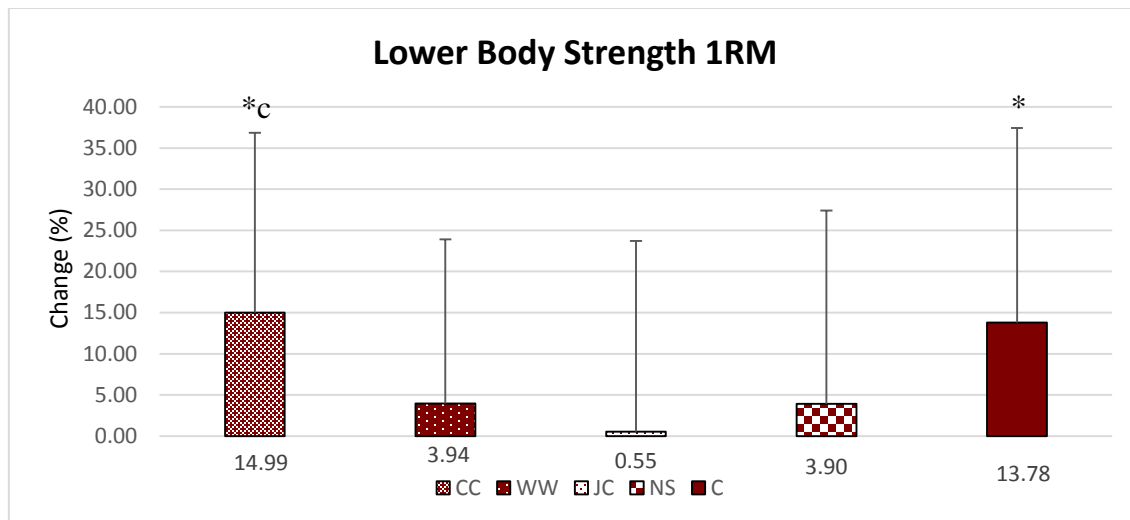


Figure 27: Changes from baseline in lower body strength 1RM after 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. n=126. When analyzed by Tukey's LSD post hoc: * significantly different from baseline ($p < 0.05$), ^c significantly different than JC ($p < 0.05$).

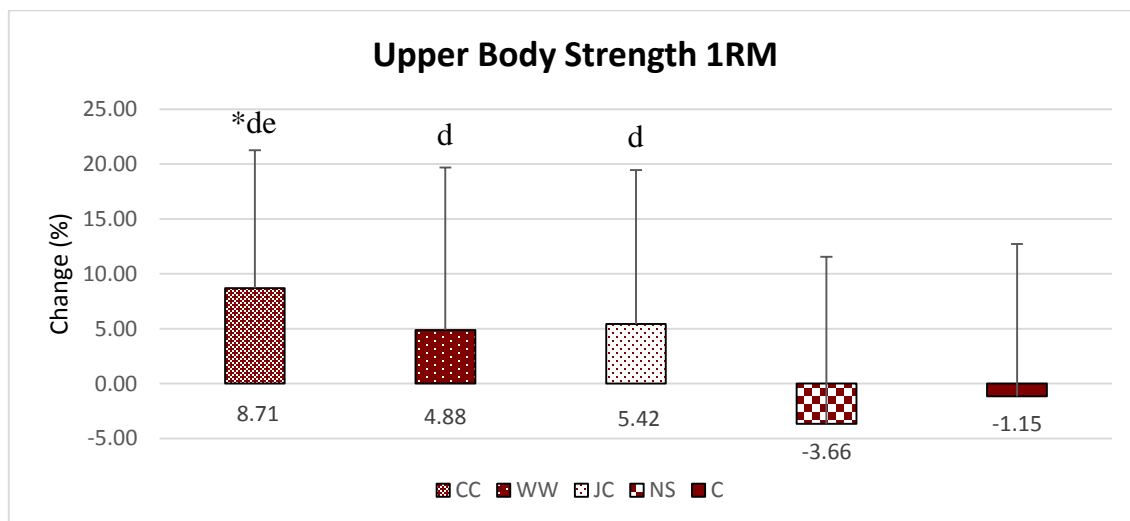


Figure 28: Changes from baseline in upper body strength 1RM after 12 weeks. Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C). Values are delta change means \pm SD. n=126. Analyzed by Tukey's LSD post hoc: * significantly different from baseline ($p < 0.05$), ^d significantly different than NS ($p < 0.05$), ^e significantly different than C ($p < 0.05$).

Psychosocial Evaluations

SF-36 Quality of Life Inventory

The SF-36 Quality of Life Questionnaire was assessed by MANOVA at 0, 4, 8, and 12 weeks of intervention. An overall time (Wilks' Lambda $p < 0.001$) and time x diet (Wilks' Lambda $p = 0.001$) effect was seen. As seen in Table 17, in the category of physical functioning, CC and WW had a significant increase from baseline at weeks 4 (CC $p = 0.001$; WW $p = 0.012$), 8 (CC $p < 0.001$; WW $p = 0.002$), and 12 (CC 13.3 ± 18.3 , $p = 0.003$; WW 8.9 ± 10.5 , $p = 0.041$). JC also did at weeks 8 ($p < 0.001$) and 12 (18.3 ± 41.0 , $p < 0.001$). The C group had a significant increase at week 4 ($p = 0.23$) and showed a trend at week 8 ($p = 0.075$). In the area of role physical, CC had a significant increase at week 8 ($p = 0.029$) and 12 (24.1 ± 68.8 , $p = 0.003$), and WW and NS also did at week 4 (WW $p = 0.027$; NS $p = 0.001$), 8 (WW $p = 0.011$; NS $p = 0.003$), and 12 (WW 46.4 ± 84.4 , $p = 0.003$; NS 24.1 ± 68.8 , $p = 0.043$). JC had significant increases at week 4 ($p = 0.018$) and 8 ($p = 0.044$). In the area of bodily pain, JC had a significant increase at week 4 ($p = 0.018$), 8 ($p = 0.014$), and a trend upward at week 12 ($p = 0.087$). NS had upward trends at week 4 ($p = 0.058$) and 8 ($p = 0.069$) as well. For general health, CC and JC had a significant increase at weeks 4 (CC $p = 0.001$; JC $p = 0.015$), 8 (CC $p < 0.001$; JC $p = 0.001$), and 12 (CC 11.9 ± 13.5 , $p < 0.001$; JC 5.2 ± 10.7 , $p = 0.036$). For the area of mental health, CC and WW had a time effect at weeks 4 (CC WW $p = 0.001$), 8 (CC $p = 0.049$; WW $p < 0.001$), and 12 (CC 6.1 ± 10.2 , $p = 0.005$; WW 5.4 ± 9.8 , $p = 0.011$). JC also did at weeks 4 ($p = 0.038$) and 8 ($p = 0.007$). When looking at role emotional, there was a significant increase for WW at weeks 4 ($p = 0.014$), 8 ($p = 0.037$), and 12 (26.2 ± 70.5 , $p = 0.047$) and for JC at week 4 ($p = 0.010$) and a trend at

Table 17: Changes in quality of life inventory. Observed between groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C)

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Physical Function	CC	76.9 ± 20	87.2 ^{†‡j} ± 17.8	90.7 ^{‡de} ± 17	90.2 ^{‡e} ± 17.1	86.3 ± 3.3	T = 0.001
	WW	78.4 ± 15.6	86.1 [†] ± 12.7	86.6 ^{‡e} ± 13	87.3 ^{‡e} ± 13.2	84.6 ± 3.2	D = 0.142
	JC	75.4 ± 18	78.3 ± 18.1	88.7 ^{‡ai} ± 9.6	93.7 ^{‡ai} ± 37.1	84.0 ± 3.3	T x D = 0.005
	NS	80.0 ^j ± 20.1	82.3 ± 18.6	80.9 ± 22	82.3 ± 22.5	81.4 ± 3.2	
	C	69.2 ± 24.9	77.8 [†] ± 19.4	75.0 [#] ± 22	72.5 ± 25.7	73.6 ± 4.0	
	Mean	76.5 ± 19.5	82.7 ± 17.4	85.0 ± 18	86.1 [*] ± 24.9		
Role Physical	CC	340.7 ± 75.4	361.1 ± 58.1	375.0 [‡] ± 48	388.0 ^{‡cd} ± 25.4	366.2 ± 10.7	T = 0.001
	WW	326.8 ± 83.6	358.9 [†] ± 57.8	366.1 [†] ± 53	373.2 ^{‡j} ± 49.5	356.3 ± 10.5	D = 0.038
	JC	325.9 ± 83.1	361.1 [†] ± 56.0	357.4 [†] ± 63	350.0 ± 66.1	348.6 ± 10.7	T x D = 0.023
	NS	312.1 ± 90.0	362.5 [†] ± 63.6	358.9 [†] ± 59	343.8 [†] ± 78.4	344.3 ± 10.5	
	C	327.8 ± 90.7	312.5 ^{abcd} ± 88.8	313.9 ^{abcd} ± 98	300.0 ^{abcd} ± 84.0	313.5 [†] ± 13.1	
	Mean	326.5 ± 83.5	354.1 ± 65.2	357.2 ± 65	354.7 [*] ± 67.6		
Bodily Pain	CC	76.0 ± 13.6	77.7 ^o ± 13.9	79.6 ^o ± 15.7	78.7 ± 13.0	78.0 ± 2.2	T = 0.028
	WW	74.5 ± 12.2	75.5 ± 13.2	77.8 ± 10.4	73.7 ± 16.6	75.4 ± 2.1	D = 0.046
	JC	72.5 ± 17.1	79.8 ^{‡e} ± 11.7	80.3 ^{‡e} ± 9.5	78.4 [#] ± 11.9	7.7 ± 2.2	T x D = 0.714
	NS	70.3 ± 18.4	76.0 ^{‡j} ± 15.1	75.9 [#] ± 16.3	75.7 ± 16.9	74.5 ± 2.1	
	C	71.2 ± 14.9	68.5 ± 18.5	71.6 ± 11.7	71.4 ± 16.2	70.7 [†] ± 2.6	
	Mean	73.0 ± 15.3	76.0 ± 14.5	77.4 ± 13.2	75.9 [*] ± 15.0		
General Health	CC	67.9 ± 12.7	76.0 ^{‡e} ± 8.7	78.0 ^{‡ai} ± 10.2	79.7 ^{‡de} ± 9.5	75.4 ± 2.5	T = 0.001
	WW	71.9 ± 14.8	74.7 ^j ± 13.6	75.2 ± 14.4	74.9 ^j ± 14.9	74.2 ± 2.4	D = 0.087
	JC	73.2 ± 14.6	78.8 ^{‡ai} ± 12.1	80.7 ^{‡de} ± 12.9	78.4 ^{‡de} ± 12.9	77.8 ± 2.5	T x D = 0.053
	NS	69.5 ± 17.1	72.4 ± 15.3	71.8 ± 16.2	70.7 ± 17.0	71.1 ± 2.4	
	C	66.8 ± 18.4	67.7 ± 17.7	69.4 ± 15.9	67.2 ± 17.3	67.8 ± 3.0	
	Mean	70.1 ± 15.4	74.3 ± 13.7	75.4 ± 14.3	74.6 [*] ± 14.9		
Mental Health	CC	61.1 ± 8.9	65.6 ^{‡e} ± 9.1	65.2 [†] ± 8.9	67.3 ^{‡de} ± 8.3	64.8 ± 1.7	T = 0.001
	WW	58.4 ± 10.6	64.6 ^{‡e} ± 8.8	66.0 ^{‡j} ± 6.6	63.9 [†] ± 11.6	63.2 ± 1.6	D = 0.073
	JC	59.7 ± 11.1	63.6 ^{‡e} ± 10.1	65.2 [†] ± 7.5	62.8 ± 10.5	62.8 ± 1.7	T x D = 0.213
	NS	59.7 ± 13.2	61.4 ± 10.6	61.7 ± 11	60.9 ± 15.2	60.9 ± 1.6	
	C	56.4 ± 12	57.6 ± 10.8	56.0 ^{abcd} ± 11	60.0 ± 9.7	57.5 ± 2.1	
	Mean	59.3 ± 11.1	62.9 ± 10	63.3 ± 9.6	63.2 [*] ± 11.5		
Role Emotional	CC	374.1 ^j ± 46.5	369.1 ± 57.7	369.1 ± 72	382.7 ^j ± 41.7	373.8 ± 10.7	T = 0.008
	WW	347.6 ± 81.9	379.8 ^{‡j} ± 52.4	375.0 [†] ± 46	373.8 [†] ± 44.8	369.0 ± 10.5	D = 0.352
	JC	342.0 ± 75.4	376.5 ^{‡j} ± 48.8	365.4 [#] ± 61.0	356.8 ± 76.1	360.2 ± 10.7	T x D = 0.504
	NS	336.9 ± 83.8	354.8 ± 65.6	346.4 ± 79	352.4 ± 85.3	347.6 ± 10.5	
	C	340.7 ± 82.9	346.3 ± 77.7	350.0 ± 71	359.3 ± 71	349.1 ± 13.1	
	Mean	348.7 ± 75.1	366.7 ± 60.2	362.0 ± 66	365.4 [*] ± 65.8		
Social Function	CC	47.7 ± 9.2	50.5 ± 10.7	51.9 [†] ± 7.5	49.5 ± 6.5	49.9 ± 0.9	T = 0.412
	WW	50.0 ^o ± 4.8	48.7 ± 7.1	49.1 ± 7.6	51.3 ^d ± 5.0	49.8 ± 0.8	D = 0.276
	JC	50.5 ^o ± 8.1	52.8 ^d ± 15.6	49.5 ± 5.4	49.8 ± 6.5	50.6 ± 0.9	T x D = 0.300
	NS	48.7 ± 5.2	46.2 ± 11.1	50.0 ± 3.4	47.8 ± 8.4	48.1 ± 0.8	
	C	45.8 ± 6.1	50.7 ± 10.9	50.0 [#] ± 8.6	48.6 ± 4.0	48.8 ± 1.0	
	Mean	48.7 ± 7.0	49.6 ± 11.5	50.1 ± 6.6	49.5 ± 6.4		

Table 17: Continued

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Vitality	CC	52.4 ± 10.5	58.9 ^{†‡e} ± 8.5	63.5 ^{†‡e} ± 10.0	63.9 ^{†‡e} ± 9.8	59.7 ± 1.9	T = 0.001
	WW	51.1 ± 13.6	57.0 ^{†‡} ± 11.2	59.5 ^{†‡} ± 10.3	58.8 ^{†‡} ± 13.1	56.6 ± 1.8	D = 0.087
	JC	52.4 ± 12.2	56.7 ^{†‡} ± 10.4	60.7 ^{†‡e} ± 7.3	56.3 ± 15.1	56.5 ± 1.8	T x D = 0.280
	NS	53.9 ± 13.9	58.6 ^{†‡e} ± 12.5	58.6 ^{†‡} ± 14.4	59.6 ^{†‡} ± 16.0	57.7 ± 1.8	
	C	49.4 ± 11.0	50.8 ± 10.3	53.1 ± 11.6	51.9 ± 11.4	51.3 ± 2.3	
	Mean	52.0 ± 12.3	56.8 ± 10.8	59.4 ± 11.2	58.6* ± 13.7		

Values are represented as means±standard deviation except group means are ±standard error mean. n = 128; CC (n=27), WW (n=28), JC (n=27), NS (n=28), and C (n=18). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p<0.05 (univariate). † = significant diet effect p<0.05 (univariate). ‡ = significant time effect from baseline p<0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC (p < 0.05). b = significantly different than WW (p < 0.05). c = significantly different than JC (p < 0.05). d = significantly different than NS (p < 0.05). e = significantly different than C (p < 0.05). # = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). f = a trend toward significance compared to CC (p > 0.05 and p < 0.1). g = a trend toward significance compared to WW (p > 0.05 and p < 0.1). h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). i = a trend toward significance compared to NS (p > 0.05 and p < 0.1). j = a trend toward significance compared to C (p > 0.05 and p < 0.1).

week 8 (p=0.078). When analyzed by MANOVA univariate, there was not a significant time (p=0.412) or diet (p=0.275) effect for the variable social function. The average change of all the groups was 0.72±9.1. For the variable vitality, a time effect was seen for CC, WW, and NS at weeks 4 (CC p=0.003; WW p=0.006; NS p=0.030), 8 (CC p<0.001; WW p=0.001; NS p=0.001), and 12 (CC 11.5±13.2, p<0.001; WW 7.7±13.2, p=0.002; NS 5.7±11.6, p=0.022). JC also had a significant increase in the area of vitality at week 4 (p=0.050) and 8 (p=0.001), though it was not significant at week 12 (3.9±15.8, p=0.123).

Body Image Questionnaire

The Body-Image Questionnaire was analyzed by MANOVA at 0, 4, 8, and 12 weeks of intervention. An overall time (Wilks' Lambda p<0.001) effect was seen. Table 18 shows that CC, WW, JC, and C all had a significant increase from baseline for appearance evaluation at weeks 4 (CC p=0.009; WW p=0.024; JC p=0.044), 8 (CC

Table 18: Changes in body image questionnaire. Observed between groups at 0, 4, 8, and 12 weeks for Curves (CC), Weight Watchers (WW), Jenny Craig (JC), Nutrisystem (NS), and Control (C).

Variable	Group	Baseline	Week 4	Week 8	Week 12	Group (SEM)	P-level
Appearance Evaluation	CC	2.49 ± 0.70	2.78 ^{td} ± 0.66	2.87 ^{td} ± 0.72	2.84 ^{td} ± 0.73	2.75 ± 0.11	T = 0.001
	WW	2.28 ± 0.73	2.52 ^{ti} ± 0.80	2.65 ^{ti} ± 0.88	2.59 th ± 0.76	2.51 ± 0.11	D = 0.061
	JC	2.25 ± 0.74	2.48 ^{ti} ± 0.70	2.62 [†] ± 0.67	2.95 ^{td} ± 0.75	2.57 ± 0.12	T x D = 0.075
	NS	2.21 ± 0.65	2.16 ± 0.74	2.33 ± 0.74	2.38 ± 0.72	2.27 ± 0.11	
	C	2.22 ± 0.51	2.54 ^{ti} ± 0.52	2.53 [†] ± 0.49	2.6.0 [†] ± 0.59	2.47 ± 0.14	
	Mean	2.30 ± 0.68	2.50 ± 0.72	2.60 ± 0.74	2.68* ± 0.74		
Appearance Orientation	CC	3.57 ± 0.46	3.55 ± 0.54	3.51 ± 0.53	3.44 ± 0.60	3.52 ± 0.09	T = 0.113
	WW	3.58 ± 0.53	3.47 ± 0.62	3.4 th ± 0.55	3.45 ± 0.54	3.47 ± 0.09	D = 0.481
	JC	3.76 ^e ± 0.60	3.53 [†] ± 0.76	3.67 ^j ± 0.67	3.63 ± 0.61	3.65 ± 0.09	T x D = 0.527
	NS	3.63 ⁱ ± 0.47	3.4 [†] ± 0.83	3.61 ± 0.45	3.52 ± 0.53	3.54 ± 0.09	
	C	3.36 ± 0.57	3.40 ± 0.60	3.36 ± 0.65	3.46 ± 0.58	3.39 ± 0.11	
	Mean	3.59 ± 0.53	3.47 ± 0.67	3.52 ± 0.57	3.50 ± 0.56		
Body Area Satisfaction	CC	2.56 ± 0.51	2.86 th ± 0.54	2.92 ^{toeh} ± 0.59	3.10 ^{toeh} ± 0.60	2.86 ± 0.09	T = 0.003
	WW	2.59 ± 0.45	2.61 ± 0.73	2.81 ^{ti} ± 0.65	2.72 ± 0.81	2.68 ± 0.09	D = 0.030
	JC	2.46 ± 0.49	2.51 ± 0.86	2.63 ± 0.60	2.79 ^{ti} ± 0.48	2.60 ± 0.09	T x D = 0.296
	NS	2.50 ± 0.65	2.45 ± 0.65	2.55 ± 0.52	2.58 ± 0.56	2.52 ± 0.09	
	C	2.46 ± 0.40	2.54 ± 0.80	2.50 ± 0.68	2.45 ± 0.65	2.49 [†] ± 0.10	
	Mean	2.52 ± 0.51	2.60 ± 0.72	2.70 ± 0.62	2.75* ± 0.65		
Overweight Preoccupation	CC	2.89 ± 0.75	3.43 [†] ± 0.86	3.31 [†] ± 0.70	3.19 ^{to} ± 0.94	3.21 ± 0.12	T = 0.001
	WW	2.82 ± 0.66	3.04 ± 0.97	3.06 ^{toed} ± 0.80	3.00 ^{ci} ± 0.87	2.98 ± 0.12	D = 0.081
	JC	2.94 ^j ± 0.57	3.33 [†] ± 1.08	3.63 ^{to} ± 0.80	3.64 ^{to} ± 0.62	3.39 ± 0.12	T x D = 0.452
	NS	3.00 ^e ± 0.68	3.27 ± 1.01	3.49 ^{ti} ± 0.70	3.34 [†] ± 0.57	3.28 ± 0.12	
	C	2.58 ± 1.02	3.09 [†] ± 1.05	3.06 [†] ± 1.10	3.14 [†] ± 0.99	3.00 ± 0.14	
	Mean	2.86 ± 0.73	3.24 ± 0.99	3.32 ± 0.80	3.26* ± 0.83		
Self-Classified Weight	CC	4.33 ± 0.74	4.24 ± 0.54	4.24 ± 0.56	4.00 ^{td} ± 0.55	4.20 ± 0.10	T = 0.004
	WW	4.34 ± 0.52	4.07 ± 1.02	4.28 ± 0.47	4.07 ^{ti} ± 0.95	4.19 ± 0.10	D = 0.606
	JC	4.46 ± 0.44	3.94 [†] ± 1.27	4.17 [†] ± 0.50	4.22 ± 0.64	4.20 ± 0.10	T x D = 0.743
	NS	4.55 ± 0.44	4.27 ± 1.01	4.30 [#] ± 0.79	4.43 ± 0.50	4.39 ± 0.10	
	C	4.48 ± 0.73	4.23 ± 1.24	4.15 [#] ± 1.08	4.08 [†] ± 1.20	4.23 ± 0.12	
	Mean	4.43 ± 0.58	4.15 ± 1.02	4.23 ± 0.68	4.16* ± 0.79		
Social Physique Anxiety	CC	31.07 ± 5.45	30.76 ± 4.16	31.38 ± 5.21	33.03 ^b ± 5.17	31.56 ± 0.86	T = 0.091
	WW	29.41 ^d ± 5.83	28.59 ± 7.71	29.69 ^c ± 4.17	29.62 ± 7.33	29.33 ± 0.86	D = 0.248
	JC	31.78 ± 5.23	29.37 ± 10.00	32.93 ^j ± 4.80	31.96 ± 5.20	31.51 ± 0.89	T x D = 0.886
	NS	32.54 ± 5.57	30.36 ± 8.43	31.54 ± 5.80	32.32 ± 5.92	31.69 ± 0.88	
	C	31.05 ± 4.93	30.25 ± 8.56	29.85 ± 9.96	30.25 ± 9.22	30.35 ± 1.04	
	Mean	31.16 ± 5.47	29.84 ± 7.86	31.13 ± 6.05	31.50 ± 6.60		
Rosenberg Self-Esteem	CC	23.83 ± 2.58	23.45 ± 1.90	23.55 ^e ± 2.65	23.31 ± 2.47	23.53 ± 0.38	T = 0.118
	WW	23.69 ± 2.41	22.62 ± 4.72	24.21 ^e ± 2.37	22.52 ^{#ci} ± 4.69	23.26 ± 0.38	D = 0.045
	JC	24.48 ^e ± 2.08	22.33 [†] ± 6.78	24.41 ^e ± 1.78	24.67 ^e ± 1.80	23.97 ± 0.40	T x D = 0.616
	NS	24.11 ⁱ ± 2.57	23.07 ± 5.14	23.54 ^j ± 2.32	24.07 ^e ± 2.05	23.70 ± 0.39	
	C	22.75 ± 2.17	22.30 ± 5.53	21.80 ± 5.65	21.80 ± 5.59	22.16 [†] ± 0.46	
	Mean	23.83 ± 2.41	22.79 ± 4.95	23.60 ± 3.12	23.35 ± 3.60		
Values are represented as means ± standard deviation except group means are ± standard error mean. n = 133; CC (n=29), WW (n=29), JC (n=27), NS (n=28), and C (n=20). T = time effect. D = diet effect. T x D = time x diet effect. * = significant time effect from baseline p < 0.05 (univariate). † = significant diet effect p < 0.05 (univariate). ‡ = significant time effect from baseline p < 0.05 (post hoc LSD). All letter superscripts represent significance or trends toward significance from post hoc LSD. a = significantly different than CC (p < 0.05). b = significantly different than WW (p < 0.05). c = significantly different than JC (p < 0.05). d = significantly different than NS (p < 0.05). e = significantly different than C (p < 0.05). # = a trend toward significance from baseline p > 0.05 and p < 0.1 (post hoc LSD). f = a trend toward significance compared to CC (p > 0.05 and p < 0.1). g = a trend toward significance compared to WW (p > 0.05 and p < 0.1). h = a trend toward significance compared to JC (p > 0.05 and p < 0.1). i = a trend toward significance compared to NS (p > 0.05 and p < 0.1). j = a trend toward significance compared to C (p > 0.05 and p < 0.1).							

$p=0.001$; WW $p=0.001$; JC $p=0.002$), and 12 (CC 0.35 ± 0.82 , $p=0.007$; WW 0.31 ± 0.55 , $p=0.016$; JC 0.70 ± 0.86 , $p<0.001$). JC had a significantly greater increase compared with WW ($p=0.033$) and NS ($p=0.005$) and showed a trend when compared to CC ($p=0.055$) at week 12. When assessing appearance orientation by MANOVA univariate, there was not an overall significant time ($p=0.113$) or diet ($p=0.448$) effect. In the category of body area satisfaction, CC had a time effect at weeks 4 ($p=0.032$), 8 ($p=0.001$), and 12 (0.54 ± 0.56 , $p<0.001$). JC also had a significant increase at week 12 (0.33 ± 0.48 , $p=0.012$). Also at week 12, CC had a greater increase in score compared to WW (0.13 ± 0.87 , $p=0.024$), NS (0.08 , 0.82 , $p=0.013$), and the C group (-0.01 ± 0.52 , $p=0.007$). In the area of overweight preoccupation, there was an increase in score for CC, JC, and C at weeks 4 (CC $p=0.004$; JC $p=0.043$; C $p=0.022$), 8 (CC $p=0.002$; JC $p<0.001$; C $p=0.003$), and 12 (CC 0.30 ± 0.78 , $p=0.043$; JC 0.69 ± 0.62 , $p<0.001$; C 0.56 ± 1.13 , $p=0.002$). NS also had an increased score at week 8 ($p<0.001$) and 12 (0.34 ± 0.53 , $p=0.026$). By week 12, JC had a significantly greater increase in scoring compared to WW ($p=0.014$) and a trend was seen when compared with CC ($p=0.067$) for overweight preoccupation. For self-classified weight, CC (-0.33 ± 0.70 , $p=0.031$) and C (-0.40 , 1.37 , $p=0.029$) had a significant decrease at week 12. By week 12, WW also showed a downward trend ($p=0.069$). JC had a decrease at week 4 ($p=0.005$) and week 8 ($p=0.046$), though not significant at week 12 ($p=0.126$). MANOVA univariate analysis showed no diet ($p=0.755$) or time x diet ($p=0.743$) effect for self-classified weight. In the category of social physique anxiety, when analyzed by MANOVA univariate, there was only a trend toward a significant time ($p=0.091$) effect and no time x diet ($p=0.886$) effect. For the variable of Rosenberg self-esteem, no overall

MANOVA univariate time ($p=0.118$) effect or time x diet ($p=0.616$) effect was observed. Due to changes seen in the SF-36 Quality of Life Questionnaire and the Body Image Questionnaire we are able to accept H_0 since statistically significant differences were observed among groups in variables relating to psychological evaluations.

Cost to Benefit Assessment

Analysis was run on food logs of 10 participants to assess the cost to benefit ratio of each group. Participants in the CC and WW groups experienced greater losses in weight (CC -0.013 ± 0.01 ; WW -0.016 ± 0.01 ; JC -0.005 ± 0.003 ; NS -0.011 ± 0.01 ; C 0.001 ± 0.016 lbs/\$, $p < 0.001$), waist circumference (CC -0.0017 ± 0.003 ; WW -0.0027 ± 0.004 ; JC -0.0006 ± 0.001 ; NS -0.0012 ± 0.002 ; C 0.0018 ± 0.006 inches/\$; $p < 0.001$), hip circumference (CC -0.0022 ± 0.002 ; WW -0.0020 ± 0.002 ; JC -0.0008 ± 0.001 ; NS -0.0016 ± 0.002 ; C 0.0008 ± 0.003 inches/\$; $p < 0.001$), fat mass (CC -4.8 ± 4.5 ; WW -4.0 ± 4.9 ; JC -1.3 ± 1.3 ; NS -2.2 ± 2.3 ; C $-0.08 \pm 0.04.8$ g/\$, $p < 0.001$), and body fat percentage (CC -0.0033 ± 0.004 ; WW -0.0014 ± 0.004 ; JC -0.0005 ± 0.0009 ; NS -0.0002 ± 0.0016 %/\$; C $-0.0001 \pm 0.004.8$, $p < 0.005$) per dollar spent compared to those in JC, NS, and C. The WW group also had a greater decrease in fat-free mass (CC -0.72 ± 2.8 ; WW -2.87 ± 3.7 ; JC -0.69 ± 0.8 ; NS -2.3 ± 2.1 ; C 0.33 ± 5.4 g/\$, $p < 0.005$) per dollar spent compared to CC, JC, NS, and C. Further, all diet groups experienced an improved peak aerobic capacity (CC 0.0034 ± 0.003 ; WW 0.0006 ± 0.010 ; JC 0.0002 ± 0.002 ; NS 0.0007 ± 0.001 ; C -0.0052 ± 0.013 ml/kg/min/\$, $p < 0.005$) per dollar spent when compared to the control.

CHAPTER V

SUMMARY AND CONCLUSIONS*

Summary

Results of the current study support findings from previous studies that weight-loss programs that incorporate resistance exercise combined with higher protein and lower carbohydrate and fat yield greater improvements in body composition. There is a greater maintenance of fat-free mass and a greater decrease in fat mass and body fat percentage as well as improving various markers of health and fitness [28, 31, 152, 209, 210]. Analysis of energy intake revealed no significant differences in energy intake at baseline, and no significant differences were seen between diet groups in average energy intake throughout the study. All groups had a decrease in energy intake, with an average intake of $1,403 \pm 427$ kcal/day. Further, all diet groups experienced a decrease in weight (-4.0 ± 4.2 kg, $p < 0.001$), body mass index (-4.0 ± 2.1 kg/m², $p < 0.001$), waist circumference (-2.7 ± 5.9 cm, $p < 0.001$), hip circumference (-3.4 ± 4.4 cm, $p < 0.001$), fat mass (-2.5 ± 3.2 kg, $p < 0.001$), body fat percentage ($-1.1 \pm 2.6\%$, $p < 0.001$), resting heart rate (-3.0 ± 9.8 bpm, $p < 0.001$), and resting systolic blood pressure (-4.1 ± 13.2 mmHg, $p = 0.005$), and an improved glucose to insulin ratio ($36.4 \pm 72.1\%$, $p = 0.001$). All diet groups also maintained relative resting energy expenditure (0.09 ± 2.03 kcal/kg/day, $p = 0.008$). Though all diet groups lost weight and had improvements in anthropometrics and various markers of health, CC had greater

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improvements in body composition, blood pressure, peak aerobic capacity, muscular strength, and hormone ratios and trended toward improvements in blood lipid ratios. These findings are similar to previous findings that following a comparative diet protocol combined with structured resistance training yields greater results [31, 152] than other weight-loss approaches. The CC diet and exercise protocol was generally more effective compared to other commercial weight-loss programs that had caloric restriction but where exercise was solely encouraged. The other commercial diets were able to provide improvements in weight-loss and waist and hip circumference as well as maintaining REE, though the CC group was able to have the same and even greater improvements while still maintaining fat-free mass and having the greatest decrease in fat mass and body fat percentage.

The findings in the present study revealed that CC was the only group with a significant increase in relative protein intake (0.15 ± 0.30 g/kg/day, $p=0.039$) combined with a decrease in relative carbohydrate intake (-0.63 ± 0.95 , $p=0.005$). Though, all diet groups experienced a decrease in fat intake, with an average decrease of -0.24 ± 0.34 g/kg/day, $p<0.001$. Additional studies that compared Weight Watchers with other commercial diet groups did not report nutritional intake [150, 160]. Further, studies that have evaluated the Jenny Craig [166, 167] and Nutrisystem [169] programs have not included a dietary breakdown of energy intake. Participants in the present study did a fairly good job achieving energy intake and macronutrient intake while following these diets compared to results in previously reported studies [31, 164, 165]. It is also important to note though, that even though the CC group was assigned a 45:25:30 PRO:CHO:FAT

ratio, participants were only able to obtain about $25.7 \pm 6.6\%$ protein in their diet on average, which is similar to previous findings, as well [31, 152, 209, 210].

Weight-loss programs that include exercise, specifically resistance exercise, may contribute to greater improvements in body composition [28, 146]. In that regard, CC had a significant increase in total physical activity ($3,801 \pm 8,668$ MET-min/wk, $p=0.012$) through the first eight weeks and had the greatest increase after 12 weeks, though not significant ($2,429 \pm 8,901$ MET-min/wk, $p=0.163$). CC also experienced the greatest decrease in fat mass (-3.8 ± 4.0 kg, $p<0.001$) and body fat % ($-2.7 \pm 3.4\%$, $p<0.001$) and was the only group that maintained fat-free mass (-0.19 ± 2.00 kg, $p=0.631$). Previous studies that have been conducted on the effectiveness of Weight Watchers, Jenny Craig, and Nutrisystem have placed a large focus on weight loss versus including other components of body composition. Our current analysis had similar findings in weight loss for the participants in WW compared to previous results [150, 158, 164]. However, Jenny Craig studies have been more long-term of 12 and 24 months [166, 167], and our NS participants did not experience as great a weight loss compared to a previous study conducted by Foster et al. [169].

The current study also found that all of the groups, except for WW, had a decrease in resting heart rate with an average decrease of -3.0 ± 9.8 bpm ($p<0.001$). CC though, was the only group to have a decrease in both systolic blood pressure (-7.6 ± 14.2 mmHg, $p=0.002$) and diastolic blood pressure (-3.6 ± 7.3 mmHg, $p=0.045$). A decrease in blood pressure was also found by Kersick and colleagues [31] in groups with comparable total energy intake and macronutrient intake combined with resistance exercise. Heart rate and

blood pressure changes in the WW group of the current study though were not significant and actually opposed previous findings by Dansinger et al. [164]. When assessing blood lipids, a trend toward a decrease in total cholesterol to HDL-cholesterol ratio ($-4.9 \pm 11.3\%$, $p=0.053$) was also seen in the CC group, and CC additionally, had the greatest increase in glucose to insulin ratio ($57.8 \pm 72.9\%$, $p=0.012$). Some differing results were observed in changes in blood lipids between the current analysis and the study by Kerkisick et al. [31] after 14 weeks of a comparable diet and exercise protocol. However, a notable similarity was that decreases in leptin levels in the four diet groups of the current study were the greatest after the first four weeks of intervention. These results compared to their findings which revealed a significant decrease after two weeks of intervention, where caloric restriction was the greatest. A study conducted by Morgan et al. [165] found that triacylglycerides, LDL-C, and HDL-C all significantly decreased in the Weight Watchers group after 2 months ($p<0.001$ for all variables). Further, Dansinger and colleagues [164] found that the subjects in Weight Watchers had a decrease of -17.9 mg/dL in total cholesterol ($p<0.01$), -14.7 mg/dL for LDL-cholesterol ($p<0.01$), and -2.2 μ IU/mL (though not significant) for insulin after 2 months. In contrast, the only significant finding in lipids or hormones in the WW group of the current study at week 8 was a significant increase in LDL-cholesterol ($1.6 \pm 23.0\%$, $p=0.045$) and a significant increase in glucose to insulin ratio ($44.7 \pm 100.0\%$, $p=0.014$). Other more long-term studies conducted with WW [160] and JC [166] found additional improvements in insulin levels. Interestingly, a focus of NS meals is the glycemic index (GI) and the goal to consume carbohydrates with a low GI. We would have expected to see significant improvements in glucose and/or

insulin levels, though neither was observed. Though a lowered GI may aid in feelings of satiety, decreasing carbohydrates without the accompaniment of resistance exercise, did not yield improvements in hormone levels. Once again, it is important to note that it would be expected that the required exercise component of the CC group would have a positive influence on markers of health, such as heart rate, blood pressure, lipids, and hormones.

Further findings of the current study showed that CC also had the greatest increase in relative peak aerobic capacity (2.5 ± 2.9 ml/kg/min, $p < 0.001$) and was also the only diet group that increased in lower body ($15.0 \pm 21.9\%$ $p = 0.001$) and upper body ($8.7 \pm 12.5\%$ $p = 0.001$) strength. This too was to be expected after participating in a supervised exercise training protocol compared to the other diet groups, where exercise was only encouraged. Rock and colleagues [167] included a step-test as part of their study design, and found that all three groups: center-based Jenny Craig, telephone-based Jenny Craig, and the usual care group all showed improvements in cardiopulmonary fitness ($p < 0.001$) as determined by the step-test protocol. However, since previous research of the other diet groups focus on a dietary intervention, the effects of those diets on fitness parameters have not been reported that we are aware. Also noteworthy, NS had the greatest intake of percent protein ($26.9 \pm 5.3\%$), though not significantly greater compared to CC ($25.7 \pm 6.6\%$, $p = 0.306$). Nonetheless, NS did not experience improvements in lower ($p = 0.365$) or upper body strength ($p = 0.182$). Which, increased protein without resistance training would not expect to yield the same improvements that were seen in the CC group. It is evident that participation in an exercise protocol, as in the CC group, led to greater improvements in cardiovascular fitness as well as muscular strength.

After assessment of the cost of each diet group, estimated total costs were (CC 879±147, WW 558±130, JC 2,600±101, NS 1,062±103, C 422±198 \$/90 days) per program. As can be seen, the JC and NS were more costly than the CC and WW approaches, which may be a limiting factor for some individuals. These findings suggest that given the efficacy, the CC program was a more cost effective approach in terms of promoting fat loss and improving body composition.

Conclusions

As supported by our findings, diets that are higher in protein and lower in carbohydrates and fat combined with a structured resistance exercise protocol may be able to produce the greatest success [28, 31, 128, 209, 210] in a weight-loss program. The central hypothesis evaluated in this study was that adherence to a higher protein, carbohydrate restricted, low fat diet while participating in a supervised resistance exercise program would result in more favorable changes in body composition and better maintenance in fat free mass and resting energy expenditure during a weight loss program. Results of the present study support this hypothesis. In this regard, participants following the CC diet and exercise program had greater increases in overall physical activity and experienced greater fat loss, better maintenance of fat free mass, and greater reductions in body fat percent compared to other diet approaches. These improvements then led to more favorable changes in various markers of fitness and health. The approach of using meal plans for diet adherence and frequent contact with exercise professionals was also more cost effective than other approaches [208].

There are several factors that could have influenced the results. First, participants in the CC group had a much greater face-to-face interaction with exercise personnel and trained with other women who were following the diet, which could have enhanced adherence and dietary compliance. Second, individuals who complete a diet and exercise program where the cost of the program is provided and compensation is provided may have greater motivation to follow the diet and exercise protocol compared to an individual who would need to cover the expenses on his/her own. Further, participants in the CC group were not allowed to continue in the study if they did not maintain at least a 75% compliance rate for workouts (three of the four per week). Additional research should investigate whether dietary supplementation with purported health and/or weight loss nutrients may provide additional benefits. Further research should also continue to evaluate the cost to benefit ratio along with which population may benefit the most from a given diet protocol. Nonetheless, results indicate that participants adhering to the CC program that incorporated a higher protein, lower carbohydrate and fat diet while participating in a supervised resistance-exercise based program was more effective than other commercial weight loss programs.

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APPENDIX A
INFORMED CONSENT

CONSENT FORM

The effects of the Curves 90-Day Fitness Challenge on health outcomes in women

Introduction

The purpose of this form is to provide you information that may affect your decision as to whether or not to participate in this research study. If you decide to participate in this study, this form will also be used to record your consent.

You have been asked to participate in a research project comparing the Curves International fitness and weight loss program to other popular weight loss programs. The purpose of this study is to determine the effects of the new Curves 90-Day Fitness Challenge on health outcomes in women. You were selected to be a possible participant because you met all entrance criteria for this study. This study is being sponsored/funded by Curves International.

What will I be asked to do?

If you agree to participate in this study, you will first be asked to sign an Informed Consent statement in compliance with the Human Subject's Protection Program (HSPP) at Texas A&M University and the American College of Sports Medicine. You will then be familiarized to the study requirements, food log recording and tests to be conducted during the study. This session will take approximately one hour to complete. Prior to reporting to the lab for baseline testing, you will record all food that you eat on dietary record forms for four days (including one weekend day). You will not exercise for 48 hours nor eat for 12 hours prior to reporting to the lab for baseline testing. You will then undergo a battery of tests as described in Table 1. You will fill out a Demographic Form, a Health History Form, A Radiation Safety Form, a Quality of Life Questionnaire, a Body Image Questionnaire and an eating Satisfaction Questionnaire. You will also be required to report any adverse side effects that you may experience on a weekly basis. .

You will then continue with the tests as described in Table 1. You will first be weighed and have your resting energy expenditure (REE) determined. This will involve lying down on an exam table and having a light blanket placed over you to keep you warm and placing ear plugs in your ears to reduce distractions. A see through plastic canopy will then be placed over your neck and head so that the air that you breathe can be measured for oxygen and carbon dioxide. You should stay motionless without going to sleep for 15-minutes so that your resting energy expenditure can be calculated. You will then donate up to approximately 30 milliliters (6 teaspoons) of venous blood from a vein in your arm. Blood samples will be obtained by standard/sterile procedures using a needle inserted into a vein in your arm and will later be analyzed. Personnel who will be taking your blood are experienced in phlebotomy (procedures to take blood samples) and are qualified to do so under guidelines established by the Texas Department of Health and Human Services. This will

take about 5-minutes. You will then have your total body water determined using a bioelectrical impedance analyzer (BIA). The BIA analysis will involve lying down on your back on a table and having two small electrodes placed on your right hand and your right foot. The analyzer wires will be attached and a small and safe current (500 micro-amps at a frequency of 5- kHz) will pass through your body so that the amount of water can be measured. This analyzer is commercially available and has been used in the health care/fitness industry as a means to assess body composition and body water for over 20 years. The use of this device has been approved by the Food and Drug Administration (FDA) to assess total body water and the current to be used has been deemed safe. Your body composition and bone density will then be determined by using a Discovery W dual energy x-ray absorptiometry (DEXA). This will involve lying down on your back on the DEXA exam table in a pair of shorts or a gown for about 6 minutes. A low dose of radiation will scan your entire body to determine the amount of fat weight, muscle weight, and bone weight. You will be exposed to an x-ray dose that is similar to the amount of natural background radiation a person would receive in one month while living in College Station. After this test, you will have resting blood pressure determined using a blood pressure cuff and stethoscope and heart rate determined by taking your pulse. You will then be prepared to perform a maximal treadmill test. You will have your right and left shoulder, right and left part of your stomach, and several places around your upper chest and below your bra line rubbed with alcohol gauze. Ten (10) electrocardiograph (ECG) electrodes will then be placed on your shoulders, chest, and stomach and you will be attached to an ECG to evaluate your heart. You will then be positioned on the treadmill and a sterile mouthpiece will be placed in your mouth and a mouthpiece holder will be placed on your head. A nose clip will be placed on your nose and that the air you breathe will be measured for oxygen and carbon dioxide content. Once the equipment is attached, you will be given instructions to begin walking on the treadmill. You will then perform an exercise test that involves increasing the speed and grade you are walking on the treadmill until you reach your maximal effort. Heart rate, ECG tracings, blood pressure and your ratings of exertion will be monitored throughout the test. Once you reach your maximum, you will undergo a slow walking and seated recovery period. This test will take about 30 minutes to complete. You will then perform a one repetition maximum (1RM) and 80% of 1RM endurance repetition test on the bench press and hip/leg sled using standard procedures. This will involve warming up and performing successive one repetition lifts on the bench press until you determine your 1 RM. You will then rest for 5-minutes and lift 80% of your 1 RM as many times as you can. You will then rest for 10-minutes and follow the same procedure in determining your 1 RM and 80% of 1 RM on the hip/leg sled. These tests will take about 20 minutes to complete. The same battery of tests will be performed at the post-study assessment 16 weeks into the study protocol. All the assessments minus the exercise tests will also be performed at 4, 6 10 and 12 weeks into the study protocol. Each testing session will take between 1.5 and 3 hours to complete. In the event of an emergency during an exercise test proper emergency response protocols (calling 9-911 for serious injury or a medical emergency, calling Biosafety/EHS for cleanup assistance or spill team response, calling UPD for incidents in public areas, retrieving AED located in the lab, performing CPR or other First Aid techniques, etc.) will be followed by the Exercise & Sport Nutrition Laboratory (ESNL) Staff depending on the severity of the emergency.

After baseline testing, you will be matched based on age, BMI, activity level and eating habits and randomized into one of six intervention groups as described in Table 2. The Operating Systems (OS) Questionnaire (or Initial Assessment) will be used to help determine the group assignments. This will include a high protein/low fat diet group (30% CHO, 45% PRO, 25% FAT, N=40), a high carbohydrate/low fat diet group (45% CHO, 30% PRO, 25% FAT, N=40), a Weight Watchers diet group (N=40), a Jenny Craig diet group (N=40), a Nutrisystem diet group (N=40) and a control group (N=40). If you are randomized into one of the first two groups (N=80 total) you will diet for 7 days at 1,200 kcals/day and then 1,500 kcals/day for the remaining 11 weeks of the study. If you are in one of the first two groups you will meet weekly one on one with your weight loss coach for the duration of the study for weekly weigh-ins. Each meeting will take place in the ESNL and will last approximately 15 minutes. The coach will guide you through each phase of the program, assist with meal planning, assist with goal setting and provide accountability and encouragement in order to meet your fitness and nutrition goals. If you are randomized into the third group (N=40) you will follow the Weight Watchers Momentum Program that is based on their four pillar approach (food, exercise, behavior and support). Every food has a POINTS value, based on its calories, fat and fiber. The Momentum program uses POINTS values to help keep track of what you eat. A POINTS “budget” will be personalized for you at the weekly meetings. You will be required to attend at least one meeting per week at the local Weight Watchers facility located at 4001 E. 29th Street, Suite 112 in the Carter Creek Center in Bryan, Texas. Membership dues/passes to the Weight Watchers program/facility will be covered for you during the duration of the study. If you are randomized into groups four or five (N=80 total), you will follow the dietary guidelines set forth by those respective plans. The sixth group (N=40) will act as a control group. If you are randomized into this group you will not follow a prescribed nutrition program but will continue with your normal daily habits. Everyone, regardless of group assignment, will keep a food record and food frequency log to monitor dietary compliance.

If you are randomized to participate in the first two groups (N=80 total) you will participate in the Curves 30-minute fitness program three times per week throughout the investigation. The Curves program involves performing thirteen hydraulic resistance exercise machines that utilize bidirectional resistance that work all major muscle groups. These are interspersed with floor-based calisthenics exercises designed to maintain an elevated heart rate. Research has shown that exercise intensity averages 65% of maximal aerobic capacity and that participants generally perform 50 – 75% of 1 repetition maximum on the main exercise machines. The new Curves equipment includes the attached force measurement and feedback system. You will be instructed to push hard enough to generate a green light on the feedback panel for each repetition. You will be instructed to wear heart rate monitors (HR) to access exercise intensity. All exercise sessions will be held in the ESNL. Research Assistants will monitor your exercise sessions and record your attendance. You will also be given a pedometer and will be recording the number of steps taken each day. On the days you do not use the Curves equipment, you will be encouraged to walk for 30-minutes at a brisk pace (60 – 80% of heart rate reserve). If you are randomized to participate in third group (N=40) you will start by focusing on the food plan and then incorporate the specifics of activity a week later once you have had the chance to get comfortable with the eating plan. After a week of reducing sedentary behavior, the POINTS Activity System is introduced. In a way that complements the POINTS values of food, a formula that calculates the POINTS values for activity is used. The

formula is based on body weight, the amount of time the activity is done, and the level of intensity. This method enables you to do any exercise or activity that is enjoyable and fits within your lifestyle. If you are assigned to groups four, five or six (N=120 total) you will not follow a prescribed exercise program but will continue your normal daily habits. Everyone, regardless of group assignment, will be required to complete activity logs to monitor exercise frequency and intensity.

Please do your best to: 1) follow the instructions outline by the investigators; 2) show up to all scheduled testing and training sessions; and 3) follow the diet prescribed and do not take any other nutritional supplements or performance enhancing aids during this study (i.e., vitamins/minerals, creatine, HMB, androstenedione, DHEA, etc). In addition, please do not take any non-medically prescribed medications and report any medication that is prescribed for you to take during this study. If you take any other nutritional supplements or medications during the course of the study that may affect vitamin/mineral status, body composition, or strength you may be removed from the study.

What are the risks involved in this study?

The risks associated with this study are: You will be exposed to a low level of radiation during the DEXA body composition tests, which is similar to the amount of natural background radiation you would receive in one month while living in College Station. In addition, a very low level of electrical current will be passed through your body using a bioelectrical impedance analyzer (BIA). This analyzer is commercially available and has been used in the health care/fitness industry as a means to assess body composition and body water for over 20 years. The use of the BIA and DEXA analyzers have been shown to be safe methods of assessing body composition and total body water and are approved by the FDA. You will donate about 6 teaspoons (30 milliliters) of venous blood four (4) times during the study using standard phlebotomy procedures. This procedure may cause a small amount of pain when the needle is inserted into the vein as well as some bleeding and bruising. You may also experience some dizziness, nausea, and/or faint if you are unaccustomed to having blood drawn. The exercise tests that will be performed may cause symptoms of fatigue, shortness of breath, and/or muscular fatigue/discomfort. The exercise tests may also cause short-term muscle soreness and moderate fatigue for several days following the tests. You may also experience muscle strains/pulls during the exercise testing and/or training program. However, exercise sessions will be conducted by trained personnel and monitored to ensure you follow appropriate exercise guidelines. You will follow a prescribed dietary regimen involving consuming 1,200 or 1,500 calories per day during various phases of the program. In addition, one group will ingest a high percentage of calories in the form of protein. Although the total amount of total protein is not excessive (100-220 grams/day or 1.1 - 2.3 grams/kg/day for a 95 kg female) it may be higher than you are accustomed to ingesting and may exceed recommended protein intake for active individuals (i.e., 1-2 grams/kg/day). As a result, you may experience weight loss or gain, feelings of hunger or fullness, and/or changes in appetite and/or mood during various phases of the dietary intervention.

What are the possible benefits of this study?

The possible benefit you may receive from participation in this study is increased physical fitness and improvements in body composition. You may also gain insight about your health and fitness status from the assessments that will be performed.

Do I have to participate?

No. Your participation is voluntary. You may decide not to participate or to withdraw at any time without your current or future relations with Texas A&M University being affected.

Will I be compensated?

You will receive \$125 (i.e., \$25 for each familiarization and experimental session) upon completion of the study. Disbursement will occur upon completion of all sessions and after all study related materials (food logs, training logs, etc.) are turned in. Those who do not complete the study will be compensated on a pro-rated basis depending on the total number of sessions completed (i.e. a participant who attends the familiarization session and completes only one experimental session is able to receive \$50).

Who will know about my participation in this research study?

The records of this study will be kept private. No identifiers linking you to this study will be included in any sort of report that might be published. Research records will be stored securely and only Mr. Christopher Rasmussen and Dr. Richard Kreider will have access to the records.

Whom do I contact with questions about the research?

If you have questions regarding this study, you may contact [REDACTED].

Whom do I contact about my rights as a research participant?

This research study has been reviewed by the Human Subjects' Protection Program and/or the Institutional Review Board at Texas A&M University. For research-related problems or questions regarding your rights as a research participant, you can contact these offices at [REDACTED] or [REDACTED].

Signature

Please be sure you have read the above information, asked questions and received answers to your satisfaction. You will be given a copy of the consent form for your records. By signing this document, you consent to participate in this study.

Signature of Participant: _____

Date:

Printed

Name:

Signature of Person Obtaining Consent: _____

Date:

Printed

Name:

APPENDIX B

PERSONAL HISTORY

Texas A&M University
EXERCISE & SPORT NUTRITION LABORATORY

Personal Information

Name: _____

Address: _____

City: _____ State: _____ Zip Code _____ SS# _____

Home Phone: (____) _____ Work Phone: (____) _____

Beeper: (____) _____ Cell Phone: (____) _____

Fax: (____) _____ E-mail address: _____

Birth date: ____ / ____ / ____ Age: _____ Height: _____ Weight: _____

Exercise History/Activity Questionnaire

1. Describe your typical occupational activities.
2. Describe your typical recreational activities
3. Describe any exercise training that you routinely participate.
4. How many days per week do you exercise/participate in these activities?
5. How many hours per week do you train?
6. How long (years/months) have you been consistently training?

APPENDIX C

MEDICAL HISTORY

Texas A&M UNIVERSITY
EXERCISE & SPORT NUTRITION LABORATORY

Medical History Inventory

Directions. The purpose of this questionnaire is to enable the staff of the Exercise and Sport Sciences Laboratory to evaluate your health and fitness status. Please answer the following questions to the best of your knowledge. All information given is **CONFIDENTIAL** as described in the **Informed Consent Statement**.

Name: _____ Age _____
Date of Birth _____

Name and Address of Your Physician:

MEDICAL HISTORY

Do you have or have you ever had any of the following conditions? (Please write the date when you had the condition in the blank).

- _____ Heart murmur, clicks, or other cardiac findings?
- _____ Asthma/breathing difficulty?
- _____ Frequent extra, skipped, or rapid heartbeats?
- _____ Bronchitis/Chest Cold?
- _____ Chest Pain or Angina (with or without exertion)?
- _____ Cancer, Melanoma, or Suspected Skin Lesions?
- _____ High cholesterol?
- _____ Stroke or Blood Clots?
- _____ Diagnosed high blood pressure?
- _____ Emphysema/lung disease?
- _____ Heart attack or any cardiac surgery?
- _____ Epilepsy/seizures?
- _____ Leg cramps (during exercise)?
- _____ Rheumatic fever?
- _____ Chronic swollen ankles?
- _____ Scarlet fever?
- _____ Varicose veins
- _____ Ulcers?
- _____ Frequent dizziness/fainting?
- _____ Pneumonia?
- _____ Muscle or joint problems?
- _____ Anemias?

- _____ High blood sugar/diabetes?
- _____ Liver or kidney disease?
- _____ Thyroid Disease?
- _____ Autoimmune disease?
- _____ Low testosterone/hypogonadism?
- _____ Nerve disease?
- _____ Glaucoma?
- _____ Psychological Disorders?

Do you have or have you been diagnosed with any other medical condition not listed?

Please provide any additional comments/explanations of your current or past medical history.

Please list any recent surgery (i.e., type, dates etc.).

List all prescribed/non-prescription medications and nutritional supplements you have taken in the last 3 months.

What was the date of your last complete medical exam?

Do you know of any medical problem that might make it dangerous or unwise for you to participate in this study?

(including strength and maximal exercise tests) _____ If yes, please explain:

Recommendation for Participation (for ESNL use only):

_____ No exclusion criteria presented. Subject is *cleared* to participate in the study.

_____ Exclusion criteria is/are present. Subject is *not cleared* to participate in the study.

Signed: _____ Date: _____

APPENDIX D

PHYSICIAN CLEARANCE FORM

Dear Provider: One of your patient's would like to participate in a study entitled "The Effects of the Curves 90-Day Fitness Challenge on Health Outcomes in Women" that is being conducted by the Exercise & Sport Nutrition Laboratory at Texas A&M University. In order to do so, she must meet the selection criteria described below and/or have approval from her personal physician to participate in the study. The study will involve having sedentary and overweight female participants participate in the Curves exercise and weight loss program, the WeightWatchers Momentum program, the Jenny Craig Program, the Nutrasystem Program or a Control Program for 12-weeks. The assessments to be performed are listed below. Please check the test/tests you **do not** feel comfortable having your patient complete (if any). In addition please staple a copy of your letterhead to this form to verify that it has been reviewed.

_____Fasting blood
expenditure (REE)

_____Fasting resting energy

_____Bench press assessments
Analysis (BIA)

_____Bioelectrical Impedance

_____Leg press assessments
(DEXA)

_____Bone densitometry

_____Diet intervention (see table attached)
cardiopulmonary stress test (Bruce Protocol)

_____Maximal

Details about these specific tests are included below and in the attached subject consent form. If you feel she meets the entrance criteria and/or any existing medical condition that she may have is under control and **would not** be a limitation for her to participate in the study, please sign the medical clearance below.

Selection Criteria

Approximately 240 sedentary and overweight female subjects (BMI > 27) between the ages of 18 and 70 will participate in this study. I understand that in order to participate in this study, a trained individual will examine me to determine whether I qualify to participate.

Participants **will not** be allowed to participate in this study if they:

1. have recent history of weight change (± 7 lb within 3 months);
2. have any metabolic disorders including known electrolyte abnormalities; heart disease, arrhythmias, diabetes, thyroid disease, or hypogonadism; a history of hypertension, hepatorenal, musculoskeletal, autoimmune, or neurological disease; if they are taking thyroid, hyperlipidemic, hypoglycemic, anti-hypertensive, or androgenic medications;
3. have been pregnant or lactating within the past 12 months or are planning to become pregnant during the next 12 months;
4. have participated in a planned exercise program or have exercised regularly (> 30 min/d 3 days/wk) within the past three months;
5. have taken any weight loss medications and/or dietary supplements that may affect muscle mass or body weight during the three month time period prior to beginning the study;

6. have any absolute or relative contraindication for exercise testing or prescription as outlined by the American College of Sports Medicine;

The only exception to these selection criteria will be if the prospective participant has a medical condition or history that the participant's personal physician feels is controlled and therefore would not be a limitation for them to participate in the study.

Medical Clearance

I medically clear _____ to participate as a subject in this study.

Name _____

Date _____

Signature _____

Diet Breakdown.

Group 1 (N=40) - Curves 90-Day Dietary Intervention Program – High Protein (HPD)

Diet Period	Energy Intake	Group	Macro-nutrient	Grams/Day	Kcals/Day	Percentage Daily Diet (%)
90 Day Fitness Challenge Phase 1 (1 Week)	1,200 kcals/d	HPD + Exercise	PRO CHO FAT	135 90 33	540 360 300	45 30 25
90 Day Fitness Challenge Phase 2 (11 weeks)	1,500 kcals/d	HPD + Exercise	PRO CHO FAT	169 113 42	675 450 375	45 30 25

Group 2 (N=40) - Curves 90-Day Dietary Intervention Program – High Carbohydrate (HCHOD)

Diet Period	Energy Intake	Group	Macro-nutrient	Grams/Day	Kcals/Day	Percentage Daily Diet (%)
90 Day Fitness Challenge Phase 1 (1 Week)	1,200 kcals/d	HCHOD + Exercise	PRO CHO FAT	90 135 33	360 540 300	30 45 25
90 Day Fitness Challenge Phase 2 (11 weeks)	1,500 kcals/d	HCHOD + Exercise	PRO CHO FAT	113 169 42	450 675 375	30 45 25

Blood Samples. Subjects will fast overnight for twelve (12) hours and then donate approximately 4 teaspoons of fasting venous blood (20 milliliters). Blood samples will be obtained using standard phlebotomy procedures using standard sterile venipuncture of an antecubital vein by laboratory technician's trained in phlebotomy in compliance with guidelines established by the Texas Department of Health and Human Services. The phlebotomists and lab technicians will wear personal protective clothing (gloves, lab coats, etc.) when handling blood samples. Subjects will be seated in a phlebotomy chair. Their arm will be cleaned with a sterile alcohol wipe and sterile gauze. A standard rubber tourniquet will then be placed on the brachium. An antecubital vein will be palpated and then a 23 gauge sterile needle attached to a plastic vacutainer holder will be inserted into the vein using standard procedures. Two serum separation vacutainer tubes (red tops) and one EDTA vacutainer tube (purple top) will be inserted into the vacutainer holder for blood collection in succession using multiple sample phlebotomy techniques. Once samples are obtained, the vacutainer holder and needle will be removed. The needle will be discarded as hazardous waste in a plastic sharps container. The site of the blood draw will then be cleaned with a sterile alcohol wipe and gauze and a sterile Band-Aid will be placed on the site. The blood collection tubes will be labeled and placed in a test tube rack for later analysis.

Resting Energy Expenditure Assessment. Resting energy expenditure assessments will be made according to standard protocols using the Parvo Medics TrueMax 2400 Metabolic Measurement System. This will involve the subjects lying down on an exam table, having a light blanket placed over them to keep warm and inserting ear plugs in their ears to reduce distractions. A see through metabolic canopy will then be placed over the subject's neck and head so that metabolic measurements can be obtained. The subject will lie motionless without going to sleep for 15-minutes. Metabolic measurements will then be obtained to determine resting oxygen uptake and energy expenditure.

Body Composition Assessments (BIA & DEXA). Subjects will undergo body composition tests in the ESNL. Prior to each assessment, height will be measured using standard anthropometry and total body weight will be measured using a calibrated electronic scale with a precision of +/- 0.02 kg. Total body water will then be estimated using a Xitron 4200 Bioelectrical Impedance Analyzer (San Diego, CA) which measures bio-resistance of water and body tissues based on a minute low energy, high frequency current (500 micro-amps at a frequency of 50 kHz) transmitted through the body. This analyzer is commercially available and has been used in the health care/fitness industry as a means to assess body composition and body water for over 20 years. The use of this device has been approved by the Food and Drug Administration (FDA) to assess total body water and the current to be used has been deemed safe. This is measured through four electrodes placed on the body: one electrode will be placed on the posterior surface of the right wrist, in between the radial and ulna styloid processes (wrist bones), another electrode will be placed on the posterior surface of the right hand at the distal base of the second metacarpal; the third electrode will be placed on the anterior surface of the right foot at the distal end of the first metatarsal. Subjects will lie on a table in the supine position and electrodes will be connected to the analyzer. After the subject is connected, age, gender, weight, height, and activity level are entered into the unit by the technician. After the unit has measured the resistance, which takes approximately 30 seconds, the unit then calculates total body water and body water percent.

Body composition/bone density will then be determined using a calibrated Hologic Discovery W dual-energy x-ray absorptiometry (DEXA) by qualified personnel with limited x-ray technology training under the supervision of Richard B. Kreider, PhD, MX. The DEXA body composition test will involve having the subject lie down on their back in a standardized position in a pair of shorts/t-shirt or a gown. A low dose of radiation will then scan their entire body for approximately six (6) minutes. The DEXA segments regions of the body (right arm, left arm, trunk, right leg, and left leg) into three compartments for determination of fat, soft tissue (muscle), and bone mass. Radiation exposure from DEXA for the whole body scan is approximately 1.5mR per scan. This is similar to the amount of natural background radiation a person would receive in one month while living in

College Station, TX. The maximal permissible x-ray dose for non-occupational exposure is 500 mR per year. Total radiation dose will be less than 5mR for the entire study. Since women of child bearing age may serve as subjects in this study, each subject will complete a questionnaire related to their menstrual cycle timing, sexual activity, use of birth control pills, and desire to become pregnant (see attached). DEXA tests will be performed within 14-days of the onset of their period in menstruating women of child bearing age who do not use oral contraceptives according to NCRP and ARP radiology standards in order to reduce the possibility of exposure of an unknown fetus to radiation.

Strength Tests. All strength/exercise tests will be supervised by certified lab assistants experienced in conducting strength tests using standard procedures. Strength testing will involve the subjects performing one repetition maximum (1 RM) on the isotonic bench press and the Nebula Fitness Olympic Power Station. Subjects will warm-up (2 sets of 8 – 10 repetitions at approximately 50% of anticipated maximum) on the bench press. Subjects will then perform successive 1 RM lifts starting at about 70% of anticipated 1RM and increasing by 5 – 10 lbs until the subject reaches their 1RM. Subjects will then rest for 10 minutes and warm-up on the Nebula 45° Leg press (2 sets of 8 – 10 repetitions at approximately 50% of anticipated maximum). Subjects will then perform successive 1RM lifts on the leg press starting at about 70% of anticipated 1RM and increasing by 10 – 25 lbs until reaching the subject's 1RM.

Cardiopulmonary Exercise Tests. Cardiopulmonary exercise tests will be performed by trained exercise physiologists in accordance to standard procedures described by the American College of Sports Medicine's (ACSM) *Guidelines for Exercise Testing and Prescription*. This will involve preparing the subject's skin s for placement of 10 ECG electrodes. Electrode sites will be cleansed with a sterile alcohol gauze using a circular motion. The site will be allowed to air dry or will be dried with a gauze pad. Electrodes will then be placed on the right subclavicular fossa (RA), left subclavicular fossa (LA), right abdomen (RL), left abdomen (LL), 4th intercostals space at the right sternal border (V1), 4th intercostals space at the left sternal border (V2), equidistant between V2 and V4 (V3), 5th intercostal space at the midclavicular line (V4), 5th intercostal space at the anterior axillary line (V5), and 5th intercostals space at the axillary line (V6) of the chest. The subject will then be attached to an ECG. Resting blood pressure, heart rate, and a 12-lead ECG will be obtained. The exercise specialist will then review the 12-lead ECG to ensure that no contraindications for exercise testing are apparent based on the ACSM guidelines. Subjects will then be seated on a treadmill. A sterile mouthpiece attached to a head harness will be secured on the subject. The subject will then have a nose clip placed on their nose. Resting expired gases will be collected using the Parvo Medics 2400 TrueMax Metabolic Measurement System. Once the subject is ready to begin the test protocol, the subject will straddle the treadmill with both legs while the treadmill is turned on at a speed of 1.7 mph and at a 0% grade. The subject will then use one foot to repeatedly swipe the belt in order to gauge the speed of the motion. Once the subject is familiar with this speed, the subject will step onto the belt while still gripping the handrail with both hands. Once the subject becomes comfortable walking on the treadmill, he/she will let go of the handrail and begin walking freely. The subject will then perform a standard symptom-limited Bruce treadmill maximal exercise test using the following speeds and grades:

Stage	Speed	Grade(%)	Duration(min.)
1	1.7	10	3
2	2.5	12	3
3	3.3	14	3
4	4.2	16	3
5	5.0	18	3

6	5.5	20	3
7	6.0	22	3

The subject will be encouraged to exercise to their maximum unless the subject experiences clinical signs to terminate the exercise test as stated by the ACSM's *Guidelines for Exercise Testing and Prescription* (i.e., angina, dyspnea, dizziness, a decline in systolic blood pressure, dangerous dysrhythmias [increasing or multi-form premature ventricular contractions, ventricular tachycardia, supraventricular tachycardia, new atrial fibrillation, or A-V block], lightheadedness, confusion, ataxia, cyanosis, nausea, excessive rise in systolic blood pressure over 250 mmHg or diastolic over 120 mmHg, chronotropic impairment, failure of the monitoring system, or other signs or symptoms for terminating the test). The test may also be terminated at the request of the subject. Once the exercise test is complete, the subject will observe a 3-6 minute active recovery period followed by a 3-6 minute seated recovery period. The normal exercise time to maximum of the Bruce treadmill protocol for untrained women is typically about 9 minutes (near the completion of stage III or just entering stage IV). Heart rate (HR), ECG tracings, and expired gases will be monitored continuously throughout the exercise test. Blood pressure (BP) and ratings of perceived exertion (RPE) will be obtained toward the end of each stage. Subjects will be asked to report any unusual signs or symptoms to the exercise specialists during the exercise test. These tests will determine maximal aerobic capacity and anaerobic threshold to determine the effects of the exercise training on fitness and exercise capacity.

APPENDIX E

PHYSICAL ACTIVITY LOG

Weekly Physical Activity Log

Name: _____ **Date:** _____

Instructions:

1. List your daily activities
 2. Assign each an intensity level – (low, moderate, high)*
 3. Indicate the duration in minutes of how long each activity lasted
- *Low intensity activities include easy walking, house chores, light gardening, etc. Moderate intensity activities include brisk walking, easy jogging, moderately-paced bicycling, etc. High intensity activities include fast running, lap-swimming, jumping rope, heavy lifting, etc.

Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Activities	Activities	Activities	Activities	Activities	Activities	Activities
Intensity:	Intensity:	Intensity:	Intensity:	Intensity:	Intensity:	Intensity:
Duration:	Duration:	Duration:	Duration:	Duration:	Duration:	Duration:

APPENDIX F DIET FOOD LOG

Name: _____

Day: 1 2 3 4 (Circle One)

Instructions:

- 1) Record everything that you eat for 3 weekdays AND 1 weekend day
- 2) Precisely record the food item (brand if applicable), preparation method, and TOTAL quantity consumed
- 3) Break down mixed dishes or recipes by listing their components
- 4) For dairy and meat products, indicate fat level (i.e. low fat, extra lean, 2%, etc.)

FOOD ITEM	PREPARATION METHOD (i.e. baked, fried, grilled, etc.)	gm	ml	cups	T or tsp.	oz.	Pieces	Sm, Med, Lg	Other
Meal 1:									
Meal 2:									
Meal 3:									

APPENDIX G
EATING SATISFACTION SURVEY

Texas A&M University – Eating Satisfaction Survey
Exercise & Sport Nutrition Laboratory

NAME _____ Date _____

INSTRUCTIONS

Circle the number or dot between numbers that best indicates the degree you have felt the following symptoms during the last week:

Appetite

None	Low	Moderate	High
Severe			
0.....	1.....	2.....	3.....4.....5.....6.....7.....8.....9.....10

Hunger

None	Low	Moderate	High
Severe			
0.....	1.....	2.....	3.....4.....5.....6.....7.....8.....9.....10

Satisfaction from Food

None	Low	Moderate	High
Severe			
0.....	1.....	2.....	3.....4.....5.....6.....7.....8.....9.....10

Feeling of Fullness

None	Low	Moderate	High							
Severe										
0	1	2	3	4	5	6	7	8	9	10

Amount of Energy

None	Low	Moderate	High							
Severe										
0	1	2	3	4	5	6	7	8	9	10

Overall Quality of Diet

None	Low	Moderate	High							
Severe										
0	1	2	3	4	5	6	7	8	9	10

APPENDIX H
RADIATION EXPOSURE

Texas A&M University

EXERCISE & SPORT NUTRITION LABORATORY

Radiation Exposure Questionnaire for Women of Child Bearing Age

Radiation exposure may affect fetal development. Although the DEXA test will only expose you to a small amount of radiation (1.5mR per scan), you should be aware that there is a possibility that if you become pregnant during the course of the study that the x-ray exposure may be harmful to the fetus. Therefore, it is important to conduct x-ray tests within 10-14 days of the start of a female's menstrual cycle if the she is of child bearing age, sexually active, and/or is not taking birth control pills. The following questionnaire must be completed so that we know when it is an appropriate time to conduct the DEXA body composition tests. Please be assured that this information will be kept confidential within the limits permitted by law.

Current Age? _____

Age of first period? _____

Date of last period? _____

Normal length of menstrual cycle? _____

Have you been sexually active within the last month? _____

Do you use birth control pills? _____

Are you pregnant or have a desire for pregnancy? _____

Note: If you happen to get pregnant during the course of this study, you must notify research assistants so that appropriate precautions can be made.

I confirm that I have completed this questionnaire honestly and agree to notify researchers within the ESNL of any change in the length of my menstrual cycle and/or pregnancy status.

Name _____ Date _____

APPENDIX I
POST STUDY QUESTIONNAIRE

Texas A&M University
Exercise & Sport Nutrition Laboratory
Post Study Questionnaire

NAME _____ Date _____

INSTRUCTIONS

Circle the number or dot between numbers that best indicates how you felt about your experience in the study.

Overall Impressions of the Curves 30-Minute Fitness Program

None	Low	Moderate	High
Severe			
0	1	2	3
4	5	6	7
8	9	10	

Overall Impressions of the Weight Loss Program

None	Low	Moderate	High
Severe			
0	1	2	3
4	5	6	7
8	9	10	

Rate the Difficulty in Adhering to the Fitness Program

None	Low	Moderate	High
Severe			
0	1	2	3
4	5	6	7
8	9	10	

Rate the Difficulty in Adhering to the Diet

None	Low	Moderate	High							
Severe										
0	1	2	3	4	5	6	7	8	9	10

Rate Your Satisfaction with the Improvements in Fitness that You Made

None	Low	Moderate	High							
Severe										
0	1	2	3	4	5	6	7	8	9	10

Rate the Satisfaction in the Changes in Body Composition that You Made

None	Low	Moderate	High							
Severe										
0	1	2	3	4	5	6	7	8	9	10

Comments/Suggestions About the Curves Fitness & Weight Loss Program